(and, as appropriate, the 1981 MOU) should be updated to clarify the effect of TSCA statutory changes, including orders and rules concerning workplace exposures for new chemical substances issued by EPA under new TSCA. Such a revision would also be an appropriate response by EPA to the directive in TSCA Section 26(*l*)(1) that EPA, within two years of enactment, develop any policies, procedures, and guidance that are determined to be necessary to carry out the amendments.

II. OSHA REGULATION OF OCCUPATIONAL EXPOSURE TO NEW CHEMICALS

OSHA has in place an extensive regulatory scheme, as well as enforcement mechanisms, governing chemical exposure in the workplace. OSHA's longstanding policy preference is to minimize workplace exposures to chemicals through engineering and process controls, which it may specify in substance-specific standards. In those circumstances where personal protective equipment (PPE) is needed to further limit worker exposure, OSHA has adopted PPE regulations; those for General Industry are found at 29 C.F.R. Part 1910, Subpart I. Section 1910.132 describes the current OSHA standards generally applicable to PPE and provides a framework for determining whether an employer has complied with those standards, while, as discussed below, respiratory protection specifically is addressed in Section 1910.134.

In a workplace inspection, OSHA's Certified Safety and Health Official (CSHO) makes the determination whether the employer has selected the particular PPE that is necessary to protect employees from identified hazards. An employer that fails to select adequate PPE generally is subject to a citation for violating 29 C.F.R. § 1910.132(d)(1)(i) unless a provision specific to the type of PPE involved applies instead. If an employer has not provided a written certification that a hazard assessment has been conducted, the inspector is directed to cite the employer for violating 29 C.F.R. § 1910.132(d)(2). If no specific PPE standard applies to the working conditions involved, or does not fully address a workplace hazard, the OSH Act's General Duty clause in Section 5(a) nonetheless requires the protection of the affected employees.

The OSH Act's General Duty clause requires every employer to furnish to each of its employees a workplace free from recognized hazards that cause, or are likely to cause, death or serious physical harm; it also requires every employer to comply with the occupational safety and health standards and all rules, regulations, and orders issued under the OSH Act. Thus, the General Duty clause adds a broad safety net and also underscores the workplace-centric nature of the OSH Act and of the intertwined responsibilities of both OSHA and individual employers in meeting specific occupational health and safety objectives. It is TSCA NCC's view that the

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General Duty clause requires employers to implement measures to prevent or to mitigate chemical exposures that may present a risk, including instances where the potential risk is identified as part of EPA's review of a new chemical substance and not fully addressed through OSHA's regulations.

OSHA also has issued detailed regulatory provisions addressing respiratory protection in the workplace; respiratory protection is disfavored as a matter of policy whenever engineering or process controls will suffice to limit occupational exposure. Respiratory protection in the form of PPE nonetheless is of particular importance for limiting chemical exposures, and is addressed both in 29 C.F.R. Subpart I at § 1910.134, as well as in various substance-specific 29 C.F.R. Part 1910 standards. The regulatory standard requires use of respirators where they are needed to protect employees from exposures to air contaminants above an exposure limit, or where they are otherwise necessary to protect employee health.

The standard places a range of responsibilities on employers as to the written respiratory protection program that must be in place, including procedures for respirator selection, use, fit, testing, cleaning, maintenance and repair; training in use and hazards; and medical evaluations of employees who use them, among other program elements. The employer is required to select and provide an appropriate respirator (National Institute for Occupational Safety and Health (NIOSH) certified) based on the respiratory hazard(s) present in the workplace, as well as workplace and user factors that affect respiratory performance and reliability. The assessment of workplace-specific hazards is a key prerequisite to the choice of the appropriate respirator; an employer who fails to assess those respiratory hazards and to select respiratory protection suitable for the purpose intended is subject to a citation for violating 29 C.F.R. § 1910.134(a)(2). Likewise, unless a substance-specific standard applies, an inspector can cite an employer for failing to provide the type of respirator needed for the substance and level of exposure involved as required under 29 C.F.R. § 1910.134(d).

TSCA NCC's review of the relevant materials does not suggest that, in enacting new TSCA, Congress intended to alter the scope of the effect of these OSHA requirements. Absent any such indication, TSCA NCC believes that the OSHA regulatory structure, including but not limited to its approach to workplace- and employee-specific PPE requirements, continues to apply where a "new" chemical substance under TSCA is involved.

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III. RECONCILING EPA'S OBLIGATION TO PROTECT AND EPA'S OBLIGATION TO CONSULT

Although EPA has an obligation to formulate and to adopt TSCA Section 5(e) orders that include measures to protect workers from exposure to new chemical substances, this duty only applies "to the extent necessary to protect against an unreasonable risk." When this duty is viewed in juxtaposition with the mandatory consultation requirement in new TSCA Section 5(f)(5), it is clear that EPA is required to evaluate the adequacy of the existing OSHA regulatory scheme, including the General Duty clause, and to adopt additional restrictions or prohibitions only when they are needed to protect against unreasonable risk.

Given the robust nature of the existing OSHA regulatory program, the proper role for EPA should be to provide hazard identification and risk assessment information that OSHA and affected employers can utilize in selecting appropriate PPE, including respiratory protection measures. For example, EPA can provide its hazard, exposure, and risk assessment information on a specific new chemical to OSHA and to the notifier, which will assist OSHA and affected employers in selecting the respiratory protection equipment and other PPE needed to comply with OSHA's regulations in 29 C.F.R. §§ 1910.134 and 1910.132. In TSCA NCC's view, when OSHA and the notifier receive EPA's hazard, exposure, and risk assessment for a new chemical substance, these materials must be considered by all employers who manufacture, process, distribute, or use the chemical in satisfying their obligation to provide a safe working environment. EPA could also make its new chemical hazard assessments more widely available, for example, by including them in its ChemView system. The chemical identity (where non-CBI), new chemical case number, and the accession number and generic name for CBI chemicals can also be included. In the case of commenced CBI new chemicals, EPA could make its appropriately sanitized hazard assessment available in responding to a *bona fide* request to ensure that future manufacturers are aware of its assessment. To ensure that this occurs, EPA could amend its *bona fide* procedures at 40 C.F.R. § 720.25 to include this step.

EPA can utilize specific restrictions in TSCA Section 5(e) consent orders to mitigate workplace exposure, but this authority is also less pervasive in nature than OSHA's broad authority to control occupational exposures. The same is true of EPA's use of Section 5(a)(2) significant new use rules (SNUR) to extend the requirements to entities beyond the notifier. Such approaches do not provide the same breadth of protection and the ongoing compliance responsibilities on the employer afforded by the OSH Act and OSHA's implementing measures. TSCA NCC believes that careful ongoing consultation with OSHA, as required under new TSCA, along with a full appreciation of the scope and effect of the OSH Act

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and OSHA's implementing measures, is essential to ensure adequate protection of all workers while also assuring that EPA only adopts separate restrictions in consent orders to the "extent necessary" to protect against an unreasonable risk.

On balance, TSCA NCC believes that EPA should disfavor issuing TSCA Section 5(e) orders that mandate use of particular PPE or other workplace-specific measures to mitigate occupational exposure. Even when the measures in question merely replicate what the applicant itself has suggested in a proposed Safety Data Sheet (SDS), such prescriptive orders have a variety of significant disadvantages. Such orders ignore OSHA's established expertise and the robust existing regulatory program, risk creating disputes over whether the EPA action has preempted OSHA's general authority to protect the involved workers, will inevitably lead to conflicts with or disputes over interpretation of parallel OSHA requirements, and may have applicability that is significantly limited by jurisdictional factors. It merits noting, as well, that OSHA does not give its approval or sign-off to the recommendations contained in SDSs and that recommendations in Section 8 of an SDS as to PPE are by no means determinative from a compliance standpoint. OSHA relies as well on its own considerable expertise, on the degree to which any industry consensus standards may be relevant, and on the impact of site- or employee-specific circumstances. For all of these reasons, TSCA NCC also believes that it is of paramount importance that to meet its obligation under Section 5(f)(5), EPA promptly should create a mechanism for the necessary ongoing consultations with OSHA. TSCA NCC further recommends that EPA act swiftly to meet its responsibilities under Section 26(*l*)(1) and commence discussions with OSHA that will lead to an update of existing MOUs to delineate clearly each agency's role in regulating exposure to new chemical substances given the changes in new TSCA.

For the reasons elaborated above, TSCA NCC is of the view that for many, if not most, of the new chemicals for which EPA has proposed workplace restrictions under TSCA, the OSH Act and OSHA's regulatory program, once EPA has informed OSHA and the notifier of its occupational risk assessment, will be sufficient to ensure workplace protection and thereby make any unreasonable risk to workers "not likely." Section 5(e) requirements to restrict workplace exposures should be reserved for those instances where EPA has determined, after consultation with OSHA, that the OSH Act and OSHA's regulatory program are not sufficient to protect against unreasonable risk from workplace exposures and that TSCA action therefore meets the "extent necessary" requirement. To the extent that EPA proceeds as recommended by TSCA NCC and relies on the OSH Act and OSHA's regulatory program, this will also have the benefit of reducing EPA's administrative burden currently spent in negotiating consent orders and promulgating SNURs for occupational concerns. Such a change in approach could also allow

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EPA to focus these regulatory resources on the potential risks to the environment and the general population -- areas that do not present the same level of overlapping authority and duplicative requirements as exist for workplace exposures.

Attachment

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- **Information Date:** 01/19/1981
- **Agreement Agency:** The Office of Pesticides and Toxic Substances and U.S. Environmental Protection Agency

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES,
U.S. ENVIRONMENTAL PROTECTION AGENCY
AND THE
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
U.S. DEPARTMENT OF LABOR
FOR

- GENERAL COOPERATION

- SHARING OF CONFIDENTIAL BUSINESS INFORMATION

- OSHA-EPA COOPERATION IN THE TSCA PREMANUFACTURE NOTIFICATION PROGRAM

- TRANSFER OF EPA INFORMATION ON SUBSTANTIAL RISK NOTICES

I. GENERAL WORKING AGREEMENT

This Memorandum of Understanding establishes a general working relationship between the Occupational Safety and Health Administration, U.S. Department of Labor, and the Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, regarding matters having or potentially having an effect on the activities and responsibilities of the two agencies.

II. COORDINATION

To achieve the coordination desired by both EPA AND OSHA, each agency hereby designates a coordinating office. The coordinating office for the Office of Pesticides and Toxic Substances (OPTS) will be the Office of Toxics Integration (OTI); for the Occupational Safety and Health Administration (OSHA), the Division of Interagency Programs. These offices shall serve as the initial communication link between the two agencies. Future specific agreements will be made by the program offices of OSHA and EPA's Office of Toxic Substances. Parts A, B and C below are directed at specific areas of coordination for sharing of confidential business information, OSHA's cooperation in the OPTS premanufacture notification program, and referral to OSHA of TSCA section 8(e) notices.

In carrying out their respective responsibilities, OPTS and OSHA will, to the extent practicable, consult and exchange information with each other through the coordinating offices. Specifically they will:

(1) Coordinate programs, including the development of standards, to avoid duplication of effort, to assist in setting priorities, and share information and research;

(2) When appropriate, consider the development of joint regulatory efforts. If no joint efforts are possible, both agencies will coordinate the development of any regulations concerning occupational exposure to new chemicals, to the extent feasible;

(3) Exchange information and report on general enforcement matters and on particular situations of common concern to each agency;

(4) Make every effort to achieve uniformity of approach in long-range planning;

(5) Obtain legal and policy positions on statutory authority regarding the extent to which the other agency can remedy a particular condition or matter that may be within the regulatory purview of the agencies;

(6) Use communication systems available to both agencies for educational services to the public about safety and health topics.

A. Confidential Business Information Exchange

PURPOSE:

This section allows OSHA to have access to confidential business information (CBI) submitted to EPA under the Toxic Substances Control Act (TSCA). OSHA will use this information to assist in fulfilling its duty to protect worker health under the Occupational Safety and Health Act of 1970.

SCOPE:

OSHA is permitted access to all confidential business information submitted to EPA under TSCA. When OSHA requests transfer of specific CBI, a justification of the need for access will be submitted through the OSHA Document Control Office (DCO) to any DCO in OPTS. OSHA will treat all such information in accordance with the Memorandum of Understanding. When OPTS initiates the transfer of CBI, a justification of OSHA's need for access should be prepared by the appropriate EPA program official and submitted to an OPTS DCO prior to the transfer of any documents containing confidential business information. The appropriate OPTS DCO must approve the justification prior to transfer of CBI.

PROVISIONS:

(1) OSHA will protect information received from EPA under this agreement by following the procedures set forth in its "OSHA TSCA Confidential Business Information Security Manual." The procedures have been approved by EPA's Inspector General's Office, and they meet or exceed the requirements of EPA's own "TSCA Confidential Business Information Security Manual."

(2) OSHA agrees that it will not release or transfer TSCA confidential business information outside of OSHA without the prior approval of EPA.

(3) OSHA will normally return confidential documents to EPA within one year, but with approval by the OPTS Document Control Officer, will be granted extensions. In addition, with approval of the OPTS Document Control Officer, OSHA may destroy the documents according to the requirements of the EPA TSCA Security Manual instead of returning them to EPA.

(4) OSHA personnel will be made aware of the possible criminal liabilities that may result from unauthorized release of CBI and will sign the TSCA-Federal non-EPA employee confidentiality agreement (Appendix 14).

(5) The Information Control Branch of the Management Support Division of OPTS (EPA) will provide initial CBI training to appropriate OSHA staff.

(6) A physical inspection of OSHA's security facilities will be made by EPA. No exchange of TSCA CBI will be made until such facilities are found to be satisfactory. There will be future periodic inspections of OSHA's security program by EPA.

(7) Following inspection and approval of OSHA's security facilities, a Federal Register notice will be published announcing this agreement and will provide the required ten days of notice, covering all future sharing of data under this section, pursuant to section 2.209 of EPA's regulations on confidentiality of business information, 40 CFR Part 2, Subpart B.

B. Premanufacture Notification (PMN) Data Exchange Procedure

PURPOSE:

This section deals with the exchange of PMN data between OSHA and OPTS. PMNs can provide information about possible worker exposure to new chemicals before they are produced on a large scale, enabling both OSHA and OPTS to discuss any possible hazards to exposed worker populations and, if necessary, coordinate action on these chemicals.

SCOPE:

OSHA and OPTS will work to assure that complete and timely notification is made concerning PMNs which may involve or affect occupational exposures to chemical hazards, and also to assure necessary coordination between OPTS and OSHA, including joint review of selected PMNs. This will permit OPTS to have the benefit of OSHA expertise in assessing occupational exposure risks, and will alert OSHA to possible chemical threats to worker health.

PROVISIONS:

To assure the above conditions are met, the following procedures are established:

(1) Contacts with OSHA concerning PMNs will be initiated by the Notice Manager for a particular PMN or by OTI through the designated individual in the OSHA Division of Interagency Programs. This individual will receive all data and information from EPA and be responsible for the response from OSHA. This individual shall coordinate the OSHA response or refer the EPA Notice Manager to the appropriate OSHA staff.

(2a) In order to assure that OSHA is informed of the status of EPA actions on PMNs, EPA's Chemical Control Division (CCD) will forward to the OSHA representative, as available, a copy of EPA's weekly PMN report. OSHA will use the report to identify PMNs of potential concern about which OSHA has not been contacted by OTI or the Notice Manager.

(2b) If the occupational exposure to a chemical is a concern during initial review, the Notice Manager or OTI will notify OSHA. EPA may request OSHA data concerning the chemical or its analogue or may refer the PMN to OSHA for information or consideration if no TSCA action is to be taken.

(2c) If a PMN for which there is concern regarding potential occupational exposure, goes into a more detailed review, the Notice Manager or OTI will notify OSHA. During the detailed review, Chemical Control Division may request technical assistance from OSHA to aid in EPA's assessment of the PMN and invite OSHA to participate in the work group.

(3) During the development of any regulatory action on a PMN for which occupational exposure is of concern, CCD will consult with OSHA. OSHA may be asked to participate in the detailed review work group for the PNM to assist in development of regulatory options. At that time, OPTS will provide OSHA with copies of documents generated by the OPTS initial review which describe the problem. As a member of this group the OSHA staff may be involved in reviewing draft regulatory actions and will be provided with a copy of the package which enters the EPA official rulemaking and clearance process.

(4) EPA will notify OSHA representatives of the final action taken by EPA on any PMN where occupational exposure is a concern.

C. Notices of Substantial Risk

PURPOSE:

This section provides a mechanism for EPA to provide OSHA with information submitted by industry under section 8(e) of TSCA, Notices of Substantial Risk.

SCOPE:

Section 8(e) of TSCA requires that any person who manufactures, processes, or distributes a chemical substance or mixture and who obtains information which reasonably supports the conclusion that the substance of mixture presents a substantial risk of injury to health or the environment shall immediately inform EPA.

For each 8(e) notice received, the OPTS Chemical Hazard Information Branch (CHIB) prepares a status report. CHIB will, by this agreement, refer to OSHA any 8(e) notices in connection with which CHIB identifies an occupational exposure of concern. OTI will coordinate any necessary follow-up work with OSHA, such as plans for further evaluation or discussion of regulatory action.

III. AUTHORITY

The Office of Pesticides and Toxic Substances enters into this agreement under the authority of Sections 9 and 14 of the Toxic Substances Control Act (15 USC 2601, et seq.). Section 9 of TSCA requires certain coordination of actions taken under TSCA with actions taken under other Federal laws. Section 14 of TSCA provides that confidential business information may be disclosed to any officer or employee of the United States in connection with the official duties of such officer or employee under any law for the protection of health or the environment.

The Occupational Safety and Health Administration enters into this agreement under authority of the Occupational Safety and Health Act of 1970 (29 USC 651, et seq.), Section 7(c)(1). That section allows the Secretary of Labor to "use, with the consent of any Federal agency, the services, facilities, and personnel of such agency, with or without reimbursement...."

IV. PERIOD OF AGREEMENT

This Memorandum of Understanding shall continue in effect unless modified by mutual assent of the parties or terminated by either party upon a 30-day advance written notice to the other party.

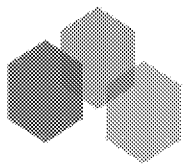
This Memorandum does not preclude the parties from entering into separate agreements setting forth procedures for special programs which can be handled more efficiently and expeditiously by such special agreement.

Nothing in this agreement is intended to diminish or otherwise affect the authority of either agency to carry out its respective statutory functions.

This Memorandum will become effective on the date of the last signature.

Marilyn C. Bracken
Associate Assistant Administrator
for Toxics Integration

Warren R. Muir
Deputy Assistant Administrator
for Toxics Substances



TSCA
NEW CHEMICALS
COALITION

December 1, 2017

Via E-Mail

Jeffery Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Jeff:

This letter is submitted on behalf of the Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC), a group of representatives from over 20 companies that have come together to identify new chemical notification issues under the amended Toxic Substances Control Act (TSCA) and to work collaboratively with you and your team to address them. Thank you for the opportunity to meet on November 16; we appreciate the discussion that we had.

One of the topics that we raised concerned the mandated consultation process with the U.S. Occupational Safety and Health Administration (OSHA) at TSCA Section 5(f)(5), and the significance of restrictions included in the Safety Data Sheets (SDS) on new chemicals. As we discussed, the TSCA NCC believes that the U.S. Environmental Protection Agency (EPA) needs to implement an appropriately robust and ongoing consultation process with OSHA "prior to adopting any prohibition or other restriction" per TSCA Section 5(f)(5) that addresses occupational exposure issues. We believe that such a procedure is needed to ensure that EPA's adoption of restrictions fully considers and avoids conflicts with OSHA's established regulatory programs in addressing and mitigating worker exposure risks to new chemical substances, a result Congress seemed to intend in amending TSCA.

Picking up on a point raised in our meeting, we note for your information that EPA's *Instruction Manual for Reporting under the TSCA § 5 New Chemicals Program*,[1] requires that the notification include, among others:

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[1] Available at https://www.epa.gov/sites/production/files/2015-06/documents/instruction_manual_2015_5-26-2015.pdf.

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- A description of each specific worker activity during which workers may be exposed to the new chemical substance. Activities must be described even if workers wear protective equipment. The SDSs indicating recommended protective equipment should be submitted as part of Hazard Information in Part I, Section C, subsection 3 of the notice form.
- Information on the specific types of protective equipment and engineering controls that will be employed to protect the worker from potential exposure to the new chemical substance (*i.e.*, type of gloves, type of goggles, National Institute for Occupational Safety and Health (NIOSH)-certified 21c respirator, NIOSH-certified 19c respirator, closed containment system, nitrogen blanket, and related measures).
- Information on the physical form of the new chemical, the maximum number of workers exposed, and the maximum duration of exposure in hours/day and days/year.

The information elements noted above are not developed strictly for EPA review purposes. These information elements are required under OSHA which, as further articulated in the attached paper, has broad authority to regulate workplace exposures. Based on these reporting requirements for new chemical reviews, EPA staff will have access to available understanding concerning occupational exposures to the new chemical and the engineering controls or personal protective equipment (PPE) that the notifier believes is needed to protect workers, and on which the notifier will be regulated under OSHA.

As discussed in more depth in the attached paper, the TSCA NCC does not believe that EPA's approach under TSCA adequately appreciates and recognizes the significance and effect of OSHA's statutory authorities and extensive regulatory scheme, as well as its enforcement mechanisms, governing workplace chemical exposures, including to new chemicals. These include:

- OSHA's detailed regulations for use of PPE when needed to further limit exposures beyond that afforded by OSHA's preferred approach of engineering and process controls. The regulatory standard, for example, requires use of respiratory protection to protect employees from exposure to air contaminants

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above an exposure limit, or where such protection is otherwise necessary to protect employee health. The standard places a range of OSHA enforced responsibilities on employers, requiring that a written program of respiratory protection must be in place including procedures for respirator selection, use, fit, testing, and so forth, training in use and hazards, and medical evaluations of employees who use such PPE.

- The General Duty clause of the Occupational Safety and Health (OSH) Act that, among other provisions, requires every employer to furnish to each of its employees a workplace free from recognized hazards that cause, or are likely to cause, death or serious physical harm. The "likely to cause" aspect of the General Duty requirement is, as you recognize, particularly relevant to new chemicals given the limited information that is often available.

We believe that Congress did not intend to alter the scope of the effect of these OSHA requirements in amending TSCA. It, however, recognized the issue of overlapping authority concerning workplace regulation of new chemicals. For this reason, while additional authority was provided to EPA in making determinations and taking required actions, Congress included the OSHA consultation provision at Section 5(f)(5) to ensure that EPA's regulation of new chemicals did not create or result in conflicts with requirements implemented by OSHA.

Although EPA has an obligation to review and make determinations regarding worker exposure issues and to formulate and adopt TSCA Section 5(e) actions that include measures to protect workers, this duty applies "to the extent necessary to protect against an unreasonable risk." When this duty is juxtaposed with the mandatory consultation requirement, it is clear that EPA is required to evaluate the adequacy of the existing OSHA regulatory scheme and to adopt additional restrictions or prohibitions only when needed to protect against unreasonable risks not otherwise addressed.

Accordingly, the proper role for EPA should be to provide hazard identification and risk assessment information to the new chemical notifier and to OSHA to make these parties fully aware of EPA's assessment and its identified occupational concerns, if any. Once informed of EPA's assessment, the employer will be known to have information that must be considered in selecting respiratory protection and other PPE needed to comply with OSHA's broadly applicable regulations and with the General Duty clause requirement that employers provide a safe working environment. By the same token, once OSHA has been informed of EPA's

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assessment, it will be in a position to enforce its regulations and to ensure that the General Duty clause requirements are being satisfied.

For these reasons, and others elaborated in the attachment, the TSCA NCC believes that EPA should disfavor issuing TSCA Section 5(e) orders that mandate use of particular PPE or other workplace-specific measures to mitigate occupational exposure. Instead, the TSCA NCC recommends the following approach if EPA identifies a workplace-specific risk concern:

1. EPA should consult with OSHA on the workplace risk concern.

2. EPA should inform the notifier of its assessment and concerns.

3. After the OSHA consultation and notifier communications are completed, EPA should no longer engage but instead rely on the employer's responsibilities mandated by OSHA, as well as OSHA's established expertise and robust existing regulatory program, to ensure worker protection.

Failure to follow a procedure as outlined above risks creating disputes over whether EPA's action preempted or created conflicts with OSHA's general authority and its regulations.

The TSCA NCC recognizes that the approach being advocated is at odds with EPA's longstanding practice in assessing and regulating new chemicals. Nonetheless, for the reasons provided above and elaborated in the attachment, TSCA NCC believes that EPA's prior and current approach is mistaken in that it does not give due recognition to OSHA's authorities and regulations and their role in ensuring a workplace free from recognized or potential occupational hazards. We believe that a modification in EPA's approach is necessary, given the changes in amended TSCA, including the OSHA consultation requirement. While EPA may have believed that, whenever an OSHA Permissible Exposure Limit (PEL) (or similar enforceable limit) is not in place, there is no enforceable requirement for companies to protect their workers from new chemical exposures, this belief is mistaken; and, as explained in this communication, does not have a basis in law or policy. Quite to the contrary, once EPA has informed the notifier and OSHA of its hazard and risk assessments, it has had the effect of triggering and setting in motion the existing regulatory requirements on employers to protect workers from recognized or likely occupational harms. Thus, any belief by EPA that, in the

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absence of a TSCA Section 5(e) or Significant New Use Rule (SNUR) requirement to protect workers, it cannot ensure the presence of an enforceable regime of workplace protections is in fact a mistaken and erroneous belief.

Put another way, EPA's current practice under amended TSCA to equate any potential health hazard to represent an unreasonable and unmanaged risk to potentially exposed workers represents a misreading of the broadly applicable and pervasive regime that is implemented and enforced based on the OSH Act and OSHA's regulations and policies. On the contrary, once appropriately informed of EPA's concerns, any employer having a commercial relationship to the notifier must be made aware of and must consider EPA's assessment conclusions and respond appropriately to meet their obligation to protect workers and provide for a safe workplace. Furthermore, the fact that OSHA has also been informed of EPA's concerns puts to rest any questions about the level of information and the hazard, exposure, and risk assessments that the notifier and affiliated employers have access to, and establishes a factual written record that can be considered during any OSHA inspections or enforcement actions.

The TSCA NCC believes that for many, if not most, new chemicals for which EPA has proposed workplace restrictions under new TSCA, once EPA has informed OSHA and the notifier of its occupational risk assessment, that will be sufficient to ensure adequate workplace protection and to make any unreasonable risk to workers "not likely." Having made such a determination regarding occupational risks, EPA should proceed to meet its obligations to assess and determine other exposure risks, such as to the environment and general population, and to take the steps required depending on the final determination. Such a change in EPA's approach would avoid the issues associated with overlapping authority and imposing duplicative, if not conflicting, requirements for workplace exposures while also allowing EPA to focus its regulatory resources on other potential risks that are not subject to the overarching and comprehensive requirements that otherwise apply in the workplace.

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We hope you find these comments helpful. We would be pleased to discuss them with you and your staff in more detail prior to the **December 6, 2017**, public workshop if that is of interest.

Sincerely,

Kathleen M. Roberts

Attachment
cc: Nancy B. Beck, Ph.D., DABT (w/attachment) (via e-mail)
Kevin W. McLean, Esquire (w/attachment) (via e-mail)
Brian P. Grant, Esquire (w/attachment) (via e-mail)

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Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 11/9/2018 5:18:43 PM
To: Baptist, Erik [Baptist.Erik@epa.gov]
Subject: EDF v. Reilly
Attachments: Environmental Defense Fund v. Reilly, 909 F.2d 1497.docx

Highlighted language begins on page 11.

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As of: November 7, 2018 2:17 PM Z

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United States Court of Appeals for the District of Columbia Circuit

January 8, 1990, Argued ; July 27, 1990, Decided

Nos. 88-5325, 88-5326

Reporter
909 F.2d 1497 *; 1990 U.S. App. LEXIS 12498 **; 285 U.S. App. D.C. 316; 20 ELR 21105; 31 ERC (BNA) 1649

Environmental Defense Fund, et al., Appellants v. William K. Reilly, Administrator, Environmental Protection Agency, et al., Appellees, Chemical Manufacturers Association, et al., Intervenors

Subsequent History: Related proceeding at [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KBB-9501-F04K-Y0PF-00000-00&context="]

Prior History: [1]** Appeals from the United States District Court for the District of Columbia.

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="]

Disposition: Affirmed.

Core Terms

rulemaking, petitions, district court, remedies, issuance, judicial review, saving clause, substances, initiate, new rule, dioxins, furans, repeal, appellants', reasons, proceedings, authorizes, statutes, parties, legislative history, denial of petition, agency's action, consent decree, de novo, requirements, promulgate, violations, provides, testing, accompanying text

Case Summary

Procedural Posture

Appellants, environmental and wildlife organizations, challenged the granting of summary judgment by the United States District Court for the District of Columbia to appellee, the Environmental Protection Agency (EPA), in the organizations' challenge to the EPA's refusal to issue rules designed to protect human health and the environment from allegedly harmful chemicals under the Toxic Substances Control Act (TSCA), [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GS01-NRF4-43JH-00000-00&context="].

Overview
In different counts of their amended complaint the organizations enlisted § 21 of the Toxic Substances Control Act (TSCA) and the Administrative Procedure Act (APA) as independent procedural vehicles. However, the end result they sought to achieve was the same: initiation of a rulemaking proceeding for the purpose of the adoption of a set of administrative actions which they proposed to the EPA. They attempted to invoke two separate remedies as means to realize a single objective. After the organizations suffered an adverse ruling on their APA approach, they chose to compromise and settle their substantive claims relief under § 21 of the TSCA. Then, having accomplished as much as they could by use of § 21, they turned again to the APA. The court held that, having thus utilized the TSCA, they could not resort to any remedy that the APA might otherwise have afforded. The court's view was that Congress had not

intended to permit a litigant challenging an administrative denial of such a petition to utilize simultaneously both the TSCA and the APA. Because the organizations pursued their TSCA remedy to ultimate settlement of their substantive claims, resort to the APA was foreclosed.

Outcome

The court affirmed the judgment of the district court that having elected to pursue the a remedy under the Toxic Substances Control Act to the results achieved by the settlement, the organizations could not then resort to the Administrative Procedures Act as well.

LexisNexis® Headnotes

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc1"][[HYPERLINK \l "Bookmark_LNHNREFclscc1"]] **Hazardous Wastes & Toxic Substances, Toxic Substances**

Section 6 is one of the most important features of the Toxic Substances Control Act. It specifies that if the Environmental Protection Agency (EPA) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment, the EPA must by rule apply one or more of prescribed requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="]. These requirements include limitations on manufacture, processing, distribution or use of such substances, [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="], [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="], [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="]; regulated methods of disposal of substances, [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="]; warnings and instructions, [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="]; notification of unreasonable risks of injury, [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="]; and preparation and retention of records pertaining to manufacture, processing, monitoring and testing. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="]. The EPA is also empowered to issue orders exacting individual compliance with the TSCA. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="].

Antitrust & Trade Law > ... > US Department of Justice Actions > Criminal Actions > General Overview

Criminal Law & Procedure > ... > Standards of Review > De Novo Review > General Overview

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

Environmental Law > Administrative Proceedings & Litigation > Jurisdiction

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-

54VD-00000-00&context=&link=LNHNREFclscc2"][[HYPERLINK \l "Bookmark_LNHNREFclscc2"]]

US Department of Justice Actions, Criminal Actions

Among a variety of mechanisms supplied for enforcement of the Toxic Substances Control Act (TSCA) are two entailing citizen activity, [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GTF1-NRF4-4288-00000-00&context="], [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. Citizen participation is broadly permitted to ensure that bureaucratic lethargy does not prevent the appropriate administration of this vital authority. 122 Cong. Rec. 32,857 (1976). One form of citizen participation is authorized by § 21 of the TSCA, [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. By virtue of [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="], any person may petition the EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule or an order under designated provisions of the TSCA. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. If the EPA grants the petition, it must promptly commence an appropriate proceeding. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. If, however, a petition requesting issuance of a new rule is denied, or the agency fails to grant or deny the request within a designated period, the petitioner may obtain de novo review in a federal district court. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. If the petitioner, once in court, meets a preponderance-of-the evidence standard, the court must order the EPA to take suitable action. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. A saving clause in § 21 of the TSCA specifies that these remedies shall be in addition to, and not in lieu of, other remedies provided by law. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

Governments > Legislation > Interpretation

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc3"][[HYPERLINK \l "Bookmark_LNHNREFclscc3"]]

Legislation, Interpretation

When it comes to statutory interpretation, the starting point is the language of the statute itself, and absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive. If, however, the language leaves the meaning of the statute unclear, the court may enlist the aid of pertinent legislative history and other sources of legislative intent in an effort to resolve the ambiguity.

Environmental Law > Administrative Proceedings & Litigation > Jurisdiction

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc4"][[HYPERLINK \l "Bookmark_LNHNREFclscc4"]]

Administrative Proceedings & Litigation, Jurisdiction

Section 21(a) of the Toxic Substances Control Act (TSCA) authorizes "any person" to petition the Environmental Protection Agency to initiate a proceeding for the issuance, amendment, or repeal of a rule under §§ 4, 6, or 8 of the TSCA, [HYPERLINK "https://advance.lexis.com/api/document?collection

=statutes-legislation&id=urn:contentItem:4YF7-GR71-NRF4-40P7-00000-00&context="], [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="], [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GTY1-NRF4-41HS-00000-00&context="]; or an "order" under §§ 5(e), or 6(b)(2) of the TSCA, [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GVT1-NRF4-452P-00000-00&context="], [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="]. Procedures for treatment of such a petition are meticulously described. Following its presentation, [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="], the EPA may convene a public hearing, conduct an investigation or look elsewhere for assistance in determining whether the petition should be granted. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. Within 90 days after filing of the petition, the EPA must either grant or deny it. If the EPA grants the petition, it must promptly commence an appropriate proceeding in accordance with §§ 4, 5, 6 or 8 of the TSCA. If the EPA denies the petition, it must publish its reasons in the Federal Register. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

Environmental Law > Administrative Proceedings & Litigation > Jurisdiction

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc5"][[HYPERLINK \l "Bookmark_LNHNREFclscc5"]] **Administrative Proceedings & Litigation, Jurisdiction**

Upon denial by the Environmental Protection Agency of a citizen petition seeking initiation of a rule, or failure to act upon such a petition in a timely manner, the petitioner may institute suit in a federal district court for an order compelling compliance with the request. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. The petitioner must be provided an opportunity to have such petition considered by the court in a de novo proceeding, [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="], and the disposition appropriate is set forth in careful detail.

Environmental Law > Administrative Proceedings & Litigation > Jurisdiction

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc6"][[HYPERLINK \l "Bookmark_LNHNREFclscc6"]] **Administrative Proceedings & Litigation, Jurisdiction**

If a petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that in the case of a petition to initiate a proceeding for the issuance of a rule under § 4 or an order under § 5(e) of the Toxic Substances Control Act (TSCA), information available to the Environmental Protection Agency (EPA) is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and in the absence of such information, the substance may present an unreasonable risk to health or the

environment, or the substance is or will be produced in substantial quantities and it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to it; or in the case of a petition to initiate a proceeding for the issuance of a rule under §§ 6 or 8 of the TSCA or an order under § 6(b)(2), there is a reasonable basis to conclude that the issuance of such a rule or order is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment. The court shall order the EPA to initiate the action requested by the petitioner.

Environmental Law > Administrative Proceedings & Litigation > Jurisdiction

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc7"][[HYPERLINK \l "Bookmark_LNHNREFclscc7"]]

Administrative Proceedings & Litigation, Jurisdiction

In considering a citizen challenge to the refusal of the Environmental Protection Agency (EPA) to promulgate a rule, if the court finds that the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which EPA is taking action under the Toxic Substances Control Act (TSCA), and there are insufficient resources available to the EPA to take the action requested by the petitioner, the court may permit the EPA to defer initiating the action requested by the petitioner until such time as the court prescribes. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. Section 21 of the TSCA is thus a comprehensive as well as an unusual remedy open to petitioners denied promulgation of new rules.

Administrative Law > Judicial Review > General Overview

Civil Procedure > Appeals > Standards of Review > De Novo Review

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

Administrative Law > Judicial Review > Standards of Review > General Overview

Civil Procedure > ... > Pleadings > Amendment of Pleadings > General Overview

Environmental Law > Administrative Proceedings & Litigation > Jurisdiction

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc8"][[HYPERLINK \l "Bookmark_LNHNREFclscc8"]]

Administrative Law, Judicial Review

Section 21of the Toxic Substances Control Act permits a petitioner to ask the Environmental Protection Agency not only for inauguration of a new rule or order, but also for amendment or repeal of a rule or order already in place. But action or inaction on petitions for amendment or repeal of a rule, unlike those for initiation of a rule, are not accorded the privilege of de novo judicial review.

Administrative Law > Judicial Review > General Overview

Civil Procedure > ... > Pleadings > Amendment of Pleadings > General Overview

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

Administrative Law > Judicial Review > Standards of Review > General Overview

Environmental Law > Administrative Proceedings & Litigation > Jurisdiction

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc9"][[

HYPERLINK \l "Bookmark_LNHNREFclscc9"]]
Administrative Law, Judicial Review

Section 21 of the Toxic Substances Control Act (TSCA), provides for different judicial review of the Environmental Protection Agency's (EPA's) denial of a petition, depending upon whether such petition seeks the issuance of a rule or order or the amendment or repeal of an existing rule or order. It affords greater rights to a person petitioning for the issuance of a rule or order because in such a situation the EPA will not previously have addressed the issue by rule or order. Less hospitable treatment of petitions to amend or repeal is warranted, then, since the EPA already will have addressed the general subject matter in an existing rule or order and its determination will have been subject to review under § 19 of the TSCA.

Administrative Law > Judicial Review > Standards of Review > General Overview

Civil Procedure > Appeals > Standards of Review > General Overview

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc10"][[HYPERLINK \l "Bookmark_LNHNREFclscc10"]]
Judicial Review, Standards of Review

Section 19 of the Toxic Substances Control Act (TSCA) provides for direct review in a federal court of appeals of rules "promulgated" under designated provisions of the TSCA. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="], [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="]. For purposes of the review, some specifications of the Administrative Procedure Act (APA), including standard of review, are modified, [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="], and as modified they govern the review process. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="], [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="]. Section 19 of the TSCA contains a saving clause similar to the one incorporated into § 21of the TSCA. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="]. Section 19 of the TSCA applies only when the Environmental Protection Agency has actually established a rule, and not where it has refused to formulate a new rule.

Administrative Law > Judicial Review > Reviewability > Preclusion

Civil Procedure > Remedies > Injunctions > Mandatory Injunctions

Administrative Law > Judicial Review > General Overview

Administrative Law > Judicial Review > Remedies > General Overview

Administrative Law > Judicial Review > Remedies > Declaratory Judgments

Administrative Law > Judicial Review > Remedies > Injunctions

Administrative Law > Judicial Review > Reviewability > General Overview

Administrative Law > Judicial Review > Reviewability > Standing

Administrative Law > Judicial Review > Standards of Review > General Overview

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

Environmental Law > Administrative Proceedings & Litigation > Judicial Review

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc11"][[HYPERLINK \l "Bookmark_LNHNREFclscc11"]]

Reviewability, Preclusion

The Administrative Procedure Act (APA) declares that a person suffering legal wrong because of an agency action is entitled to judicial review thereof. *5 U.S.C.S. § 702*. This provision is qualified by the inapplicability of the APA to situations wherein statutes preclude judicial review, *5 U.S.C.S. § 701(a)(1)*, or an agency action is committed to agency discretion by law. *5 U.S.C.S. § 701(a)(2)*. The form of proceeding for judicial review, the APA states, is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. *5 U.S.C.S. § 703*. Indubitably, § 21 of the Toxic Substances Control Act has all the character of the special statutory review provision spoken of.

Administrative Law > Judicial Review > Administrative Record > General Overview

Civil Procedure > Appeals > Standards of Review > De Novo Review

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

Administrative Law > Judicial Review > Reviewability > General Overview

Administrative Law > Judicial Review > Standards of Review > General Overview

Administrative Law > Judicial Review > Standards of Review > De Novo Standard of Review

Environmental Law > Administrative Proceedings & Litigation > Judicial Review

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc12"][[HYPERLINK \l "Bookmark_LNHNREFclscc12"]]

Judicial Review, Administrative Record

The remedies of § 21 of the Toxic Substances Control Act (TSCA) and the Administrative Procedure Act (APA) are incompatible in major respects, a circumstance inveighing against the theory that Congress sanctioned concurrent use of both. The plaintiff in a proceeding under § 21 of the TSCA is entitled to de novo consideration of his petition for issuance of a new rule, but APA review, save in rare instances, must be conducted on the administrative record. The plaintiff under § 21 of the TSCA must demonstrate, by a preponderance of the evidence, a risk affecting health or the environment; on APA review, the agency's action must be evaluated on the record. While the court, proceeding de novo under § 21 of the TSCA, is free to disregard the Environmental Protection Agency's reasoning and decision, APA review is restricted under *5 U.S.C.S. § 706* and highly deferential. If the plaintiff under § 21 of the TSCA carries his burden and the court makes any one of the statutorily-specified determinations, the court itself directs the disposition to be made of the petition. On the other hand should a district court on APA review find agency action defective, either substantively or procedurally, it ordinarily must remand to the agency for further proceedings.

Administrative Law > Judicial Review > Reviewability > General Overview

Civil Procedure > ... > Jurisdiction > Jurisdictional Sources > General Overview

Environmental Law > Hazardous Wastes & Toxic Substances > Toxic Substances

Administrative Law > Judicial Review > Standards of Review > General Overview

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc13"][[

HYPERLINK \l "Bookmark_LNHNREFclscc13"]]
Judicial Review, Reviewability

The Toxic Substances Control Act (TSCA) places § 21 review squarely in the lap of the federal district court. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. Jurisdiction to review a final rule promulgated under the TSCA lies exclusively in the court of appeals. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="]. The proper forum for Administrative Procedure Act review of a denial of a petition for a new rule or order, if that remedy is available, is far less clear.

Business & Corporate Compliance > ... > Real Property Law > Zoning > Building & Housing Codes

Civil Rights Law > ... > Contractual Relations & Housing > Fair Housing Rights > General Overview

Governments > Federal Government > US Congress

Governments > Legislation > Interpretation

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=LNHNREFclscc14"][[HYPERLINK \l "Bookmark_LNHNREFclscc14"]]
Zoning, Building & Housing Codes

Absent plain statutory language or convincing indication to the contrary, federal courts will not impute to Congress an intention to uproot wholesome precepts interwoven into the fabric of jurisprudence.The normal rule of statutory construction is that if Congress intends for legislation to change the interpretation of a judicially created concept, it makes that intent specific.

Counsel: Mark Van Putten, with whom Karen Florini was on the brief, for Appellants.

David C. Shilton, Attorney, Department of Justice, with whom Robert L. Klarquist and Fred R. Disheroon, Attorneys, Department of Justice, and Alan Carpien, Attorney, Environmental Protection Agency, were on the brief, for Appellees.

Edward S. Warren, with whom Timothy S. Hardy, James R. Walpole, Andrew A. Giaccia, David F. Zoll and Matthew B. Van Hook were on the brief, for Intervenors.

Judges: Wald, Chief Judge, Ruth Bader Ginsburg, Circuit Judge, and Robinson, Senior Circuit Judge. Opinion for the Court filed by Senior Circuit Judge Robinson.

Opinion by: ROBINSON

Opinion

[*1497] ROBINSON, Senior Circuit Judge.

Appellants, the Environmental Defense Fund and the National Wildlife Federation, jointly petitioned the Environmental Protection Agency (EPA) [1] to issue, pursuant to the Toxic Substances Control Act, [2] **[**3]** rules designed to protect human health and the environment from allegedly harmful dioxins and furans. EPA denied the petition in major part, whereupon appellants brought this suit in the **[**2]** District Court. Appellants contended that EPA's disposition of their request for rulemaking contravened the Administrative Procedure Act (APA). [3] Appellants also invoked Section 21 of the Toxic Substances Control Act, which authorizes citizen petitions seeking promulgation of rules and orders under designated provisions thereof, and affords an opportunity for de novo district-court review of denials **[*1498]** of such petitions. [4] The

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[1] Appellees herein are EPA, its Administrator and three other EPA officers. We refer to them collectively as EPA. Intervenors are the Chemical Manufacturers Association, a participant in the District Court, and the American Paper Institute.

[2] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GS01-NRF4-43JH-00000-00&context="].

[3] See ***5 U.S.C. § 706 (1988)***.

[4] See [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-

District Court awarded summary judgment to EPA on appellants' APA challenge, and that ruling is the subject of these appeals. The court later entered a consent decree settling all of appellants' Section 21 claims. We hold that appellants, having elected to pursue the Section 21 remedy to the results achieved by the settlement, cannot now resort to the APA.

I. BACKGROUND

A. *The Toxic Substances Control Act*

Enactment of this legislation in 1976 launched a "comprehensive program" [5] to anticipate and forestall injury to health and the environment from activities involving toxic chemical substances. [6] Congress structured the Act to fill "conspicuous gaps" in the protection afforded by preexisting "fragmented and inadequate" statutes, [7] and committed administration of the Act to EPA. [8] A brief resume of the Act's highlights serves the purposes of these appeals.

[4]** The Act provides in Section 4 for substance testing, [9] and in Section 5 for notice of intent to manufacture new substances or existing substances for significant new uses. [10] Section 6 requires imposition of restrictions when the substance is hazardous, [11] and Section 7 authorizes judicial proceedings for injunctive and other relief when danger is imminent. [12] Section 8 calls for retention and reporting of information, [13] and Section 10 for research, monitoring and dissemination of data. [14]

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc1"][[HYPERLINK \l "Bookmark_clscc1"]] Section 6 is one of the most important features of the Act. It specifies that if EPA

> finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk of injury to health or the environment, [the agency **[**5]** must] by rule apply one or more of [prescribed] requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements. [15]

These requirements include limitations on manufacture, processing, distribution or use of such substances; [16]

GSY1-NRF4-4217-00000-00&context="].

[5] H.R. Rep. No. 1341, 94th Cong., 2d Sess. 7 (1976).

[6] *Id.* at 1-7. See also [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GS01-NRF4-43JH-00000-00&context="] (findings, policy and purpose of the Act).

[7] H.R. Rep. No. 1341, *supra* note 5, at 6, 7.

[8] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSD1-NRF4-4248-00000-00&context="].

[9] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GR71-NRF4-40P7-00000-00&context="].

[10] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GVT1-NRF4-452P-00000-00&context="].

[11] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="].

[12] *Id.* § 2606.

[13] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GTY1-NRF4-41HS-00000-00&context="].

[14] *Id.* § 2609.

[15] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="].

[16] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="], [

regulated methods of disposal of substances; [17] warnings and instructions; [18] notification of unreasonable risks of injury; [19] and preparation and retention of records pertaining to manufacture, processing, monitoring and testing. [20] EPA is also empowered to issue orders exacting individual compliance with the Act. [21]

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc2"][[HYPERLINK \l "Bookmark_clscc2"]] Among a variety of mechanisms supplied for enforcement of the Act [22] **[**7]** are two entailing **[*1499]** citizen activity. [23] Citizen participation **[**6]** is broadly permitted to "ensure that bureaucratic lethargy does not prevent the appropriate administration of this vital authority." [24] One form of citizen participation is authorized by Section 21, [25] and is central to the parties' dispute. By virtue of that section, "any person may petition [EPA] to initiate a proceeding for the issuance, amendment, or repeal of a rule . . . or an order" under designated provisions of the Act. [26] If EPA grants the petition, it must "promptly commence an appropriate proceeding." [27] If, however, a petition requesting issuance of a new rule is denied, or the agency fails to grant or deny the request within a designated period, the petitioner may obtain de novo review in a federal district court. [28] If the petitioner, once

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[17] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="].

[18] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="].

[19] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="].

[20] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="].

[21] E.g., *id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="].

[22] For example, the Act provides for assessments of civil penalties for violations of rules or orders issued conformably to its terms, *id.* § 2615(a), and criminal penalties for violations found to be knowing or willful. *Id.* § 2615(b). Violations may be restrained, *id.* § 2616(a)(1)(A), (B), and substances produced through violations may be seized. *Id.* § 2616(b).

[23] Citizens may bring civil actions to restrain violations of the Act, or to require EPA to perform nondiscretionary acts. *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GTF1-NRF4-4288-00000-00&context="]. Citizens may also petition EPA for issuance, amendment or repeal of rules and orders fashioned under specific provisions of the Act. *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[24] 122 Cong. Rec. 32,857 (1976) (statement of Sen. Tunney).

[25] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[26] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[27] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[28] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection

in court, meets a preponderance-of-the evidence standard, the court must order EPA to take suitable action. [29] A saving clause in Section 21 specifies that "the[se] remedies . . . shall be in addition to, and not in lieu of, other remedies provided by law." [30]

B. *The Procedural History*

In 1984, appellants jointly petitioned EPA, [31] "solely under the authority of section 21," [32] to promulgate rules under Sections 4, 6 and 8 to curtail releases of dioxins and furans into the environment. [33] **[**9]** The petition further requested imposition of Section 8 record-keeping and reporting requirements, ostensibly to enable monitoring of the results. [34] The petition also asked that, should EPA lack **[**8]** sufficient data to make the threshold finding required by Section 6, [35] a testing rule be issued under Section 4 to gather whatever additional information might be needed. [36]

EPA denied the petition to the extent that it sought substantive rulemaking under Section 6 "because [it did] not believe sufficient information existed to issue such rules." [37] **[**10]** The petition was also rejected insofar as EPA felt that appellants' concerns **[*1500]** should be redressed under other federal statutes. [38] EPA explained that "it lacked critical information to decide whether all of the isomers of concern present an unreasonable risk," [39] but announced that it was

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=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[29] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[30] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. We analyze § 21 more thoroughly in Part II *infra*.

[31] Petition of the Environmental Defense Fund and the National Wildlife Federation for Rulemakings to Prevent and to Reduce Environmental Contamination by Dioxins and Dibenzofurans [hereinafter Petition], Appellees' Supplemental Appendix (S. App.) 9.

[32] *Id.* at 1, S. App. 14.

[33] The petition listed these supplications:

> (1) Set health-based standards stipulating concentration limits in *products* the synthesis of which results in contamination by the specified [dioxins and furans].
>
> (2) Require the safe handling of all wastes contaminated by the specified [dioxins and furans] to channel them away from air emissions and water discharges into controlled solid waste streams.
>
> (3) Ban land and ocean disposal and underground injection of wastes contaminated by the specified [dioxins and furans].
>
> (4) Limit stack emissions from incineration of all waste contaminated by the specified [dioxins and furans] and for other wastes which upon combustion may result in the formation of the specified [dioxins and furans].
>
> (5) Promulgate health-based effluent prohibitions for these chemicals; establish water quality criteria for the specified [dioxins and furans].
>
> (6) Take measures to control nonpoint source runoff of the specified [dioxins and furans].

Petition, *supra note* 31, at 3, S. App. 16 (emphasis in original).

[34] *Id.* at 11-12, S. App. 24-25.

[35] See text *supra* at note 15.

[36] Petition, *supra* note 31, at 93, S. App. 106.

[37] Dioxin and Furan Pollution; Partial Grant of Environmental Defense Fund/National Wildlife Federation Citizens' Petition, [HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-1S40-001T-91B4-00000-00&context="].

[38] [HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-1S40-001T-91B4-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-1S40-001T-91B4-00000-00&context="].

[39] [HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-1S40-001T-91B4-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-

"granting the petition by commencing administrative proceedings to determine whether findings sufficient to support initiation of a rulemaking proceeding under section 4 and/or 8 may be made," [40] and pledged that it would "consider issuing section 6 rules when sufficient data are obtained." [41]

Thereupon, appellants sued in the District Court. In Count I of their complaint, they applied for Section 21 de novo review of EPA's refusal to proceed with substantive rulemaking under Section 6. [42] In Counts II through VIII, they sought judicial testing of EPA's decision by the standards established by the APA. [43] The court, deeming unavailable any APA review of denials of Section 21 petitions seeking issuance of new rules, [44] granted EPA's motion for summary judgment with respect to Counts II through VIII. [45] The court perceived "an inherent illogic to [appellants'] contention that a petition denial is simultaneously subject to both *de novo* and APA review," [46] and opined that its ruling **[**11]** was "further underscored by section 21's complete lack of substantive standards governing the agency's consideration of such petitions." [47] By the court's assessment, neither the section's saving clause [48] nor any other of the sundry grounds advanced by appellants [49] sufficed as a basis for APA review of the

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1S40-001T-91B4-00000-00&context="]. See also [HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-1S40-001T-91B4-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-1S40-001T-91B4-00000-00&context="].

[40] *Id.* See also [HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-1S40-001T-91B4-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-1S40-001T-91B4-00000-00&context="].

[41] [HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-1S40-001T-91B4-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:3SDB-1S40-001T-91B4-00000-00&context="]. EPA has since issued final rules requiring testing of certain chemical substances under § 4 for dioxin-furan contamination and reporting under § 8. 40 C.F.R. pt. 766 (1989).

[42] Amended Complaint, *EDF v. Thomas*, Civ. No. 85-973 (D.D.C.) (filed June 6, 1985) paras.44-60, S. App. 157-160.

[43] *Id.* paras.61-98, S. App. 160-168.

[44] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="].

[45] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="]. We agree with the court that EPA's favorable response to the petition's § 4 request did not moot the controversy. See [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="].

[46] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="].

[47] *Id.*

[48] *Id.*

[49] [HYPERLINK "https://advance.lexis.com/api/document?collection

action taken on appellants' petition. [50]

[12]** C. *The Settlement Agreement*

Before the District Court addressed Count I, which sought Section 21 review, the parties agreed to a settlement of all substantive claims asserted in that count. This agreement was incorporated into an elaborate consent decree, [51] which the District Court "entered as [its own] Order." [52] The decree states that it was "entered for the exclusive purpose of compromising and settling Count I of the" amended complaint; [53] it recites that "the parties wish to settle the dispute" so described; [54] and it provides that "this decree shall apply to and be binding upon the parties to this action, and upon the officers, successors, agents, employees and assigns of the parties." [55]

[13]** The consent decree directs EPA to investigate the need to promulgate rules and orders to redress appellants' concerns, and, within prescribed time limits, to either commence **[*1501]** appropriate proceedings or announce its refusal to do so. [56] The decree states that it is in "full satisfaction of all claims" embraced by Count I or assertible under Section 21 with respect to dioxin-furan regulation under the Act of activity which other agency-administered statutes empower EPA to deal with. [57] The decree provides that its entry also constitutes entry of final judgment on Counts II-IX, [58] and binds appellants to move for dismissal of Count I with prejudice when EPA completes the tasks required by the agreement. [59]

D. *The Parties' Contentions*

Appellants maintain that the District Court erred in holding that APA review of administrative denials **[**14]** of Section 21 new-rule petitions is legally out of reach. They argue that "nothing in the language or legislative history of [the Act] explicitly indicates congressional intent to preclude APA review of citizens' petition denials." [60] They point particularly to the "'strong presumption'" that agency decisions are subject to judicial review, [61] and to Section 21's saving clause as evidence of congressional intent to preserve APA review of petition denials. [62] Appellants also take issue with the District Court's holding that there are no standards by which Section 21 new-rule petitions can be judged, and consequently that decisions thereon are committed wholly to agency discretion. [63]

=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="].

[50] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="]. The court also entered summary judgment for EPA on the amended complaint's Count IX, see [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="], charging agency failure to perform unspecified nondiscretionary duties allegedly imposed by the Act. That disposition was not appealed.

[51] Consent Decree, *EDF v. Thomas*, No. 85-0973 (D.D.C.) (filed July 27, 1988), Appendix to Brief for Appellants (A. App.) at 13 [hereinafter Consent Decree].

[52] *EDF v. Thomas*, Civ. No. 85-0973 (order) (filed July 27, 1988), A. App. 12.

[53] Consent Decree, *supra* note 51, para. 2, A. App. at 13.

[54] *Id.* para. 2, A. App. 13-14.

[55] *Id.* para. 6, A. App. 15.

[56] *Id.* PP. 15-27, A. App. 16-28.

[57] *Id.* P. 33, A. App. 30.

[58] *Id.* P. 34, A. App. 30.

[59] *Id.* P. 32, A. App. 30.

[60] Brief for Appellants at 16.

[61] *Id.* at 14 (quoting [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-W780-0039-M2TM-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-W780-0039-M2TM-00000-00&context="].

[62] Brief for Appellants at 17-18.

[63] *Id.* at 24-33.

EPA, backed by the intervenors, responds with the argument that when "Congress provides a specific remedy **[**15]** . . . that remedy is presumed to be exclusive." [64] The question, EPA says, is "not whether review is precluded but whether the statutory review procedure is exclusive." [65] EPA points out that APA review is unavailable where there is an adequate alternative remedy, and insists that Section 21 confers such a remedy. [66] EPA warns that appellants' broad reading of Section 21's saving clause "would render meaningless particular restrictions or requirements which Congress placed on the express remedies, such as the burden of proof requirement" of Section 21. [67] EPA contends additionally that there are no standards by which agency denials of Section 21 new-rule petitions may be evaluated, [68] and asserts that no live controversy remained after the parties joined in the consent decree settling Count I of the amended complaint. [69]

[16]** We affirm the District Court's judgment without venturing as far abroad as that court did. While undoubtedly the scope of APA review of an agency's denial of a petition for rulemaking is "extremely limited," [70] the cases before us do not necessitate a determination as to whether APA review of agency denials of Section 21 new-rule petitions is totally precluded. Our view much more simply is that Congress did not intend to permit a litigant challenging an administrative denial of such a petition to utilize simultaneously both Section 21 and the APA. Because appellants pursued their Section 21 remedy to ultimate settlement of their substantive claims, we hold that resort to the APA is now foreclosed. **[*1502]** We need not and do not decide whether APA review would have been available to appellants had they chosen that route exclusively.

[17]** II. THE FRAMEWORK OF SECTION 21

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[64] Brief for Appellees at 17.

[65] *Id.*

[66] *Id.* at 17-21.

[67] *Id.* at 24.

[68] *Id.* at 27-33.

[69] *Id.* at 13 n.6; Brief For Intervenors at 3-6; see also Brief For Appellants at 11 n.11.

[70] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RTP-9630-0039-W008-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RTP-9630-0039-W008-00000-00&context="] (emphasis and citation omitted). Accord, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-XWG0-003B-G083-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-XWG0-003B-G083-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-W780-0039-M2TM-00000-00&context="] note 61, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-W780-0039-M2TM-00000-00&context="].

[71] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-76J0-003B-S17P-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-76J0-003B-S17P-00000-00&context="]. Accord, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-H870-003B-4555-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-H870-003B-4555-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BG40-0039-

however, the language leaves the meaning of the statute unclear, the court may enlist the aid of pertinent legislative history and other sources of legislative intent in an effort to resolve the ambiguity. [72] These twin guidelines shape our approach to the problem whether appellants may utilize the APA as a basis for their attack on EPA's disposition of their petition.

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc4"][[HYPERLINK \l "Bookmark_clscc4"]] Section 21(a) authorizes "any person" to petition EPA "to initiate a proceeding for the issuance, amendment, or repeal" of a "rule" under Sections 4, [73] 6 [74] or 8, [75] or an "order" under Sections 5(e) [76] or 6(b)(2) [77] of the Act. [78] Procedures for treatment of such a petition are meticulously described. Following its presentation, [79] EPA may convene a public hearing, conduct an investigation or look elsewhere for assistance in determining whether the petition should be granted. [80] Within 90 days after filing of the petition, EPA must either grant or deny it. [81] If EPA grants the petition, it

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N538-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BG40-0039-N538-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6HV0-001B-K1G3-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6HV0-001B-K1G3-00000-00&context="].

[72] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HST0-003B-41RR-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HST0-003B-41RR-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-G390-003B-41NY-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-G390-003B-41NY-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-04H0-001B-K0TW-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-04H0-001B-K0TW-00000-00&context="].

[73] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GR71-NRF4-40P7-00000-00&context="].

[74] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="].

[75] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GTY1-NRF4-41HS-00000-00&context="].

[76] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GVT1-NRF4-452P-00000-00&context="].

[77] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSP1-NRF4-451J-00000-00&context="].

[78] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[79] See *id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="] (place of filing and content of petition).

[80] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[81] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

must "promptly commence an appropriate proceeding in accordance with" Sections 4, 5, 6 or 8 of the Act. [82] If **[**19]** EPA denies the petition, it must publish its reasons in the Federal Register. [83]

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc5"][[HYPERLINK \l "Bookmark_clscc5"]] Upon denial of a petition seeking initiation of a rule, or failure to act upon such a petition in a timely manner, the petitioner may institute suit in a federal district court for an order compelling compliance with the request. [84] The petitioner must "be provided an opportunity to have such petition considered by the court in a de novo proceeding," [85] and the disposition appropriate is set forth in careful detail:

> [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc6"][[HYPERLINK \l "Bookmark_clscc6"]] If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that --
>
> > (i) in the case of **[**20]** a petition to initiate a proceeding for the issuance of a rule under section [4] . . . or an order under section [5(e)] . . . --
> > (I) information available to [EPA] is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and
> >
> > (II) in the absence of such information, the substance may present an unreasonable risk to health or the environment, or the substance is or will be produced in substantial quantities and **[*1503]** it enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to it; or
> >
> > (ii) in the case of a petition to initiate a proceeding for the issuance of a rule under section [6] or [8] . . . or an order under section [6(b)(2)], . . . there is a reasonable basis to conclude that the issuance of such a rule or order is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment. [86]
>
> the court shall order [EPA] to initiate the action requested by the petitioner. [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc7"][[HYPERLINK \l "Bookmark_clscc7"]] If the court finds that the extent of **[**21]** the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which [EPA] is taking action under this [Act] and there are insufficient resources available to [EPA] to take the action requested by the petitioner, the court may permit [EPA] to defer initiating the action requested by the petitioner until such time as the court prescribes. [87]

Section 21 thus is a comprehensive as well as an unusual remedy open to petitioners denied promulgation of new rules.

As we have seen, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc8"][[HYPERLINK \l "Bookmark_clscc8"]] Section 21

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[82] *Id.*

[83] *Id.*

[84] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[85] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[86] The period following "environment" appears in the original. The reviser notes that the period probably should be a semicolon.

[87] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

permits a petitioner to ask EPA not only for inauguration of a new rule or order, but also for amendment or repeal of a rule or order already in place. [88] But action **[**22]** or inaction on petitions for amendment or repeal of a rule, unlike those for initiation of a rule, are not accorded the privilege of de novo judicial review. The statutory language strongly suggests that, and the legislative history makes it plain and explains why Section 21 is written that way. The Senate Report, speaking of a petition for issuance of a new rule, states the reason:

> In a judicial review of [EPA's] denial of a citizen's petition or failure to act, there would be no record upon which the review could be based, and therefore a *de novo* procedure is essential to provide the opportunity to develop such a record. [89]

The Conference Reports further inform us that [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc9"][[HYPERLINK \l "Bookmark_clscc9"]] Section 21

> provides for different judicial review of the [agency] denial of a petition, depending upon whether such petition seeks the issuance of a rule or order or the amendment or repeal of an existing rule or order. . . . [It] affords greater rights to a person petitioning for the issuance of a rule or order because in such a situation the [agency] will not previously have addressed the issue by rule or order. [90] **[**24]**

Less hospitable treatment of petitions to amend **[**23]** or repeal is warranted, then, since "the [agency] already will have addressed the general subject matter in an existing rule or order and [its] determination will have been subject to review under section 19 of th[e] Act." [91] This difference in treatment is significant; the Conference Reports make it known that

> the conferees do not intend that [EPA] be subjected to constant petitions challenging rules or orders for which adequate judicial review is provided under section 19. Therefore, if [EPA] denies a petition to amend or repeal an action under section 4, 5(e), 6, or 8, [Section 21] permits review of such denial only under **[*1504]** the Administrative Procedure Act. [92]

[HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc10"][[HYPERLINK \l "Bookmark_clscc10"]] Section 19, to which the Conference Committee referred, provides for direct review in a federal court of appeals of rules "promulgated" under designated provisions of the Act. [93] For purposes of the review, some specifications of the APA, including standard of review, are modified, [94] and as modified they govern the review process. [95] Section 19 contains a saving clause similar to the one incorporated into Section 21. [96] **[**25]** Section 19, of

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[88] See text *supra* at notes 73-78.

[89] S. Rep. No. 698, 94th Cong., 2d Sess. 13 (1976), *reprinted in* [1976] U.S. Code Cong. & Admin. News 4491, 4502-4503 [hereinafter Senate Report].

[90] S. Rep. No. 94-1302, 94th Cong., 2d Sess. 98 (1976) [hereinafter Senate Conference Report]; H.R. Conf. Rep. No. 1679, 94th Cong., 2d Sess. 98 (1976), *reprinted in* [1976] U.S. Code Cong. & Admin. News 4583 [hereinafter House Conference Report].

[91] Senate Conference Report, *supra* note 90, at 98; House Conference Report, *supra* note 90, at 98.

[92] Senate Conference Report, *supra* note 90, at 99; House Conference Report, *supra* note 90, at 99.

[93] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="], [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="].

[94] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="].

[95] *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="], [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="].

[96] "The remedies as provided in this section shall be in addition

course, applies only when EPA has actually established a rule, and not where, as here, it has refused to formulate a new rule. [97]

[26]** Emerging from this analysis are two standards of the Act's scheme of judicial review of EPA action on petitions for rulemaking, and complete silence of the statutory text with respect to the third. Denials of petitions seeking initiation of new rules may be reviewed in district courts in Section 21 proceedings and the review may be de novo. Refusals to amend or repeal existing rules can be reviewed in courts of appeals in modified APA proceedings. But the Act does not expressly address the question of APA review of denials of new-rule petitions, and the search for the answer must continue.

III. CONSTRUCTION OF SECTION 21

Appellants urge us to view their litigative effort through the lens of a potent presumption that EPA's disposition of their rulemaking petition is subject to APA review. [98] To be sure, the APA "creates a strong presumption of reviewability that can be rebutted only by a clear showing that judicial review would be inappropriate," [99] but that does not authenticate the proposition appellants advance. The presumption to which they refer relates to a choice between judicial reviewability and judicial unreviewability, not to the procedure by which the review is to **[**27]** occur if at all. This the APA itself makes perfectly apparent.

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to and not in lieu of any other remedies provided by law." *Id.* [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="].

[97] Independently of other legislation, the APA itself authorizes petitions for rulemaking. "Each agency," it proclaims, "shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule," ***5 U.S.C. § 553(e) (1982)*** -- language closely similar to that found in § 21. Moreover, refusals to engage in requested rulemaking constitute final agency action normally though narrowly reviewable in accordance with the APA. [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-XWG0-003B-G083-00000-00&context="] note 70, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-XWG0-003B-G083-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RTP-9630-0039-W008-00000-00&context="] note 70, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RTP-9630-0039-W008-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-W780-0039-M2TM-00000-00&context="] note 61, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-W780-0039-M2TM-00000-00&context="]. Appellants' rulemaking petition did not cite the operationally duplicative APA provision; their petition stated that it was filed "solely under the authority of section 21." See note 32 *supra* and accompanying text. Nonetheless, we recognize it as additional authorization for the filing of the petition.

[98] Brief for Appellants at 14.

[99] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-W780-0039-M2TM-00000-00&context="] note 61, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-W780-0039-M2TM-00000-00&context="]. Accord, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3DB0-003B-S3CJ-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3DB0-003B-S3CJ-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-83V0-003B-S189-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-83V0-003B-S189-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-FXG0-003B-S4DB-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-FXG0-003B-S4DB-00000-00&context="].

"https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc11"][[HYPERLINK \l "Bookmark_clscc11"]] The APA declares that "[a] person suffering legal wrong because of agency action . . . is entitled to judicial review thereof." [100] **[**29]** This provision is qualified by the inapplicability of the APA to situations wherein "statutes preclude judicial review" [101] or "agency action is committed to agency discretion by law." [102] But for the **[*1505]** presence of Section 21, appellants might **[**28]** have qualified for APA review of EPA's denial of their rulemaking petition by invoking the presumption of reviewability - a matter on which we intimate no opinion. As it actually was, however, no need to presume reviewability ever arose, for Section 21 obviously conferred reviewability, albeit in the manner specified in that section. "The form of proceeding for judicial review," the APA states pertinently,

> is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. [103]

Indubitably, Section 21 has all the character of "the special statutory review provision" spoken of, and plainly it is "relevant to the subject matter" of this litigation. [104]

[30]** This brief examination suffices to demonstrate

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[100] ***5 U.S.C. § 702 (1988)***. See also *id.* § 704 ("agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review").

[101] ***5 U.S.C. § 701(a)(1) (1988)***.

[102] ***5 U.S.C. § 701(a)(2) (1988)***. The Supreme Court has made clear that this exception to APA review "is applicable in those rare instances where 'statutes are drawn in such broad terms that in a given case there is no law to apply.'" [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-DR60-003B-S41D-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-DR60-003B-S41D-00000-00&context="] (quoting S. Rep. No. 752, 79th Cong., 1st Sess. 26 (1945)) (footnote omitted). See also [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-C3G0-0039-N12B-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-C3G0-0039-N12B-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-94V0-001B-K2PB-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-94V0-001B-K2PB-00000-00&context="].

[103] ***5 U.S.C. § 703 (1988)***.

[104] Compare [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6WW0-0039-X0Y5-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6WW0-0039-X0Y5-00000-00&context="]. See also [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-TXT0-0039-Y23G-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-TXT0-0039-Y23G-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-Y1H0-001B-K0KM-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-Y1H0-001B-K0KM-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-0R50-003B-G3BG-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-0R50-003B-G3BG-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-30M0-0039-P3XG-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-30M0-0039-P3XG-00000-00&context="].

that the presumption of reviewability does not validate appellants' thesis that EPA's ruling on their rulemaking petition must withstand not only their Section 21 assault but also testing by the APA's criteria. [105] Appellants have not confined themselves to the APA remedy; rather, they have endeavored to utilize both the APA and the Section 21 remedies. Thus the question confronting us is not whether APA review is available singly in lieu of Section 21 review, but whether appellants are entitled to both.

The language of the Toxic Substances Control Act does not itself yield a clear answer to this pivotal question. When, however, we scrutinize as a whole the statutory text, the legislative history, the structure of the Act and the respective roles of Section 21 and the APA, we are constrained to conclude that Congress did not intend to authorize simultaneous utilization of the two remedies.

In the first **[**31]** place, that technique would be out of tune with the announced objective and carefully defined operation of Section 21. That section was incorporated into the Act as a means of producing, through a de novo proceeding in a district court, a record enabling an informed decision on the validity of an agency denial of a petition for issuance of a new rule. [106] A statute is to be construed in light of the purpose the legislature sought to serve, [107] **[**32]** and Section 21's mission is antagonistic to use of the two remedies concomitantly. And since Congress fashioned the Section 21 remedy to elevate effective judicial review to a degree perhaps unattainable otherwise, it would be rash to assume that Congress expected - let alone authorized - a petitioner to expend governmental as well as personal resources in pursuit of the infirm remedy alongside the healthy one. Statutory **[*1506]** construction leading to an absurd result is to be avoided. [108]

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[105] See ***5 U.S.C. § 706 (1988)***.

[106] See notes 89-92 *supra* and accompanying text.

[107] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-8830-003B-S1RY-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-8830-003B-S1RY-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-GVH0-003B-S4B9-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-GVH0-003B-S4B9-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-H9D0-003B-S0H5-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-H9D0-003B-S0H5-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-YB40-003B-G3G2-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-YB40-003B-G3G2-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-0JS0-0039-X0R4-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-0JS0-0039-X0R4-00000-00&context="], *cert. denied*, ***415 U.S. 951, 94 S. Ct. 1475, 39 L. Ed. 2d 567 (1974)***; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-0Y70-0039-Y4T2-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-0Y70-0039-Y4T2-00000-00&context="].

[108] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-5DC0-003B-S4DH-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-5DC0-003B-S4DH-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-5JW0-003B-S0VK-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-5JW0-003B-S0VK-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-TDH0-0039-M0VH-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-TDH0-0039-M0VH-00000-00&context="] & n.89, [

Beyond that, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc12"][HYPERLINK \l "Bookmark_clscc12"]] the Section 21 and the APA remedies are incompatible in major respects, a circumstance inveighing against the theory that Congress sanctioned concurrent use of both. The plaintiff in a Section 21 proceeding is entitled to de novo consideration of his petition for issuance of a new rule, [109] but APA review, save in rare instances, must be conducted on the administrative record. [110] The Section 21 plaintiff must demonstrate, by a preponderance of the evidence, a risk affecting health or the environment; [111] on APA review, the agency's action must be evaluated on the record. [112] **[**34]** While the Section 21 court, **[**33]** proceeding de novo, is free to disregard EPA's reasoning and decision, APA review is restricted [113] and highly deferential. [114] If the Section 21 plaintiff carries his burden and the court makes any one of the statutorily-specified determinations, [115] the court itself directs the disposition to be made of the petition. [116] On the other hand should a district court on APA review find agency action defective, either substantively or procedurally, it ordinarily must remand to the agency for further proceedings. [117] It is difficult to believe that Congress intended to indulge a disappointed petitioner

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[109] See note 87 *supra* and accompanying text.

[110] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-1DK0-0039-M10J-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-1DK0-0039-M10J-00000-00&context="] (collecting authorities).

[111] See note 87 *supra* and accompanying text.

[112] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4MN0-003B-S3TH-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4MN0-003B-S3TH-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-JTY0-003B-S06W-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-JTY0-003B-S06W-00000-00&context="].

[113] See ***5 U.S.C. § 706 (1988)***.

[114] See [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3BF0-003B-S30X-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3BF0-003B-S30X-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4MN0-003B-S3TH-00000-00&context="] note 112, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4MN0-003B-S3TH-00000-00&context="].

[115] See note 87 *supra* and accompanying text.

[116] See note 87 *supra* and accompanying text.

[117] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-JGX0-003B-S19J-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-JGX0-003B-S19J-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-H6B0-0039-P54B-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-H6B0-0039-P54B-00000-00&context="] (remand necessary "when there is a significant chance that but for the errors the agency might have reached a different result").

in side-by-side use of remedies so incongruent.

Contemporaneous resort to Section 21 and the APA, moreover, could rather easily produce wholly inconsistent rulings. For example, a Section 21 de novo proceeding, in which the plaintiff has the burden of showing a threat to **[**35]** health or environment, could lead to a decision coinciding with EPA's outcome, while APA review, involving examination of the agency's reasons as well as its result, could necessitate a remand. Indeed, it is not beyond the realm of possibility that a plaintiff seeking review under both Section 21 and the APA would engender a jurisdictional clash -- district-court authority over the Section 21 claims, and court-of-appeals authority over the others. [118]

Even more disturbing to us is the terrible waste of time, energy, money and tranquility inherent in any mixture **[**36]** of Section 21 and APA remedies which does not gain an outright victory for the plaintiff on his plea for rulemaking. Put another way, a citizen petitioner for issuance of a new rule, no matter how doggedly and successfully he pursues APA claims of agency error, can never achieve his ultimate goal unless and until he persuades EPA or the reviewing **[*1507]** court that health or environmental concerns warrant the rulemaking he seeks. If, for instance, after the Section 21 battle has been fought to a finish and the reviewing court's ruling is adverse to the plaintiff under that section, but favorable to him under the APA, all that has been accomplished is a remand to EPA for further proceedings consistent with the law. Those proceedings would extend to reconsideration of the agency's original decision to deny rulemaking, and the Section 21 battle would resume, this time before EPA. Even if that transpired in an error-free manner but the petitioning citizen again lost before EPA, he would have to do battle again in a new Section 21 proceeding in court. How much easier it would have been for all concerned if that plaintiff had discarded any thought of joining Section 21 and the APA as **[**37]** twin mechanisms for review, and had simply used his APA ammunition to expose the agency's errors as flaws in the chain of reasoning eventuating in rejection of the rulemaking request.

At this point, we think, the longstanding policy of the law to avoid duplicative litigative activity comes to the fore. Strands of this policy are readily discernible among the underpinnings of several specific legal rules designed to minimize expense and inconvenience to litigants and conserve the finite resources of the courts. [119] We

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[118] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc13"][HYPERLINK \l "Bookmark_clscc13"]] The Act places § 21 review squarely in the lap of the district court. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="]. Jurisdiction to review a final rule promulgated under the Act lies exclusively in the court of appeals. [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GHC1-NRF4-40B9-00000-00&context="]. See text *supra* at notes 93-95. The proper forum for APA review of a denial of a petition for a new rule or order, if that remedy is available, is far less clear.

[119] As prominent examples, the doctrines of election of remedies, see [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-42X0-003B-H233-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-42X0-003B-H233-00000-00&context="], and law of the case, see [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-VY80-003B-T2S7-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-VY80-003B-T2S7-00000-00&context="]; the rule proscribing splitting of an indivisible cause of action, see [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BBR0-003B-74VS-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BBR0-003B-74VS-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-1KD0-0039-X36Y-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-1KD0-0039-X36Y-00000-00&context="]; and the judicial preference for initial review of administrative action in the

hasten to emphasize that we do not rest our decision upon any of these rules as such. What we do is look to one of the concepts centrally underlying them for guidance in discharging our interpretive responsibilities.

[38]** [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3N50-003B-54VD-00000-00&context=&link=clscc14"][[HYPERLINK \l "Bookmark_clscc14"]] Absent plain statutory language or convincing indication to the contrary, federal courts will not impute to Congress an intention to uproot wholesome precepts interwoven into the fabric of our jurisprudence. [120] **[**40]** In *Jones v. Alfred H. Mayer Co.*, [121] the Supreme Court refused to "assume that Congress intended to effect any change, either substantive or procedural" [122] in a 98-year-old "general statute [123] applicable only to racial discrimination in the rental and sale of property and enforceable only by private parties acting on their own initiative," by enactment of "a detailed housing law [124] applicable to a broad range of discriminatory practices and enforceable by a complete arsenal of federal authority." [125] In *Callanan v. United States*, [126] the Court, adverting to "the distinctiveness between a substantive offense and a conspiracy to commit [as] a postulate of our law," [127] readily "attribute[d] 'to Congress a tacit purpose - in the absence of any

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courts of appeals, see [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-C360-0039-N126-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-C360-0039-N126-00000-00&context="]; [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-1C40-0039-X2PH-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-1C40-0039-X2PH-00000-00&context="], *cert. denied*, ***414 U.S. 1001, 94 S. Ct. 356, 38 L. Ed. 2d 237 (1973)***.

[120] "The normal rule of statutory construction is that if Congress intends for legislation to change the interpretation of a judicially created concept, it makes that intent specific." [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-8HB0-0039-N0WN-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-8HB0-0039-N0WN-00000-00&context="] (citing [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-8100-003B-S11P-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-8100-003B-S11P-00000-00&context="], (1979)).

[121] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-FHV0-003B-S04N-00000-00&context="].

[122] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-FHV0-003B-S04N-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-FHV0-003B-S04N-00000-00&context="].

[123] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GKP1-NRF4-42CH-00000-00&context="].

[124] Civil Rights Act of 1968, Pub. L. No. 90-284, tit. VIII, 82 Stat. 81 (codified at ***42 U.S.C. §§ 3601 et seq. (1982)***).

[125] *Jones v. Alfred H. Mayer Co., supra* note 121, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-FHV0-003B-S04N-00000-00&context="].

[126] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HMF0-003B-S491-00000-00&context="].

[127] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HMF0-003B-S491-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HMF0-003B-S491-00000-00&context="].

inconsistent expression -- to maintain a long-established distinction between offenses essentially different; a distinction **[*1508]** whose practical importance in the criminal law is not easily over-estimated. **[**39]** '" [128] Similarly, in *Cole v. Young*, [129] the Court, finding it "difficult to justify summary suspensions and unreviewable dismissals on loyalty grounds of employees who are not in 'sensitive' positions and who are thus not situated where they could bring about any discernible adverse effects on the Nation's security," [130] would "not lightly assume that Congress intended to take away [their procedural] safeguards in the absence of some overriding necessity, such as exists in the case of employees handling defense secrets." [131] And in *St. Regis Paper Co. v. United States*, [132] **[**41]** the Court acknowledged "the duty to avoid a construction that would suppress otherwise competent evidence unless the statute, strictly construed, requires such a result." [133] It would take considerably more than appellants have offered to persuade us that Congress, in formulating Section 21, contemplated an interpretation allowing duplicative litigation of their substantive claims via the APA.

Appellants, however, point to the saving clause embodied in Section 21, which states that "the remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law." [134] **[**43]** Taken literally, this provision might superficially appear to preserve the right to APA review for which appellants so vigorously contend. That result does not follow nearly so readily, for the Supreme Court has made clear that saving clauses are not to be read so naively. In *Middlesex County Sewerage Auth. v. National Sea Clammers Ass'n*, [135] an organization of watermen sued governmental officials and entities for alleged violations of the Federal Water Pollution Control Act [136] and the

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[128] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HMF0-003B-S491-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HMF0-003B-S491-00000-00&context="] (quoting [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-72J0-003B-H2X8-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-72J0-003B-H2X8-00000-00&context="].

[129] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-J8J0-003B-S4P7-00000-00&context="].

[130] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-J8J0-003B-S4P7-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-J8J0-003B-S4P7-00000-00&context="].

[131] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-J8J0-003B-S4P7-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-J8J0-003B-S4P7-00000-00&context="].

[132] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HD70-003B-S1MV-00000-00&context="].

[133] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HD70-003B-S1MV-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HD70-003B-S1MV-00000-00&context="].

[134] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[135] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-69P0-003B-S07X-00000-00&context="].

[136] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GPP1-NRF4-40KG-00000-00&context="].

Marine Protection, Research and Sanctuaries Act of 1972. [137] Each of those statutes has a saving clause as broad as Section 21's, yet the Court held that a *Section 1983* suit for damages [138] could not be maintained. [139] "It is hard to believe," the Court said, "that Congress intended to preserve the *[Section 1983]* right of **[**42]** action when it created so many specific statutory remedies, including . . . two citizen-suit provisions." [140] Turning to the saving clauses, the Court concluded that Congress did not intend to perpetuate that right of action for substantive violations of either of the two statutes:

> The legislative history makes clear Congress' intent to allow further enforcement of anti-pollution standards arising under *other* statutes or state common law. A suit for damages asserting a substantive violation of [either of the two acts] is far different, even if the *remedy* asserted is based on the separate right of action created in *§ 1983*. [141]

Thus the Court looked beyond the literal meaning of the saving clauses to legislative history indicative of a contrary meaning. In the litigation before us, the saving clause in Section 21 is susceptible to more than one reading, and we have been equally sensitive to a responsibility to take due **[*1509]** account of other considerations pertinent to its proper interpretation. [142]

Appellants also refer us to Section 21's direction **[**44]** to EPA to publish in the Federal Register its reasons for denying a rulemaking petition. [143] **[**45]** We accept that requirement as an indication of congressional intent to aid judicial review in some measure. We realize that publication of reasons may serve other than as a starting point for such review, [144] but we regard additional purposes as too slight to discount appreciably the assistance those reasons might lend to reviewing courts. Appellants assert, however, that preclusion of APA review would render superfluous Section 21's call for publication since the agency's reasons are immaterial in a subsequent de novo review proceeding.

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[137] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GR61-NRF4-40DB-00000-00&context="].

[138] See ***42 U.S.C. § 1983 (1982)***.

[139] *Middlesex County Sewerage Auth. v. National Sea Clammers Ass'n, supra* note 135, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-69P0-003B-S07X-00000-00&context="].

[140] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-69P0-003B-S07X-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-69P0-003B-S07X-00000-00&context="].

[141] [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-69P0-003B-S07X-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-69P0-003B-S07X-00000-00&context="] (emphasis in original).

[142] Section 21's saving clause is not a dead letter. For instance, as the District Court stated, "petitioners would still have a right to APA review if and when the agency took some type of final action -- if, for example, it issued a rule pursuant to section 6 or testing rule under section 4." [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="][HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="] note 44, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="].

[143] See text *supra* at note 83.

[144] The District Court observed that the requirement may "demonstrate[] to the petitioners that their concerns have been adequately considered and addressed," and that "it may help frame the issues for a Section 21 suit." [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="] note 44, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="].

[145] That argument is unconvincing because publication of reasons is demanded whenever EPA turns down a Section 21 petition, whether or not the denial is subject to de novo review. [146] Even more fundamentally, the statutory call for publication, whatever its importance in other debates might be, has no significance to the question at hand - whether appellants may resort to APA review in addition to Section 21 review of EPA denials of new-rule petitions.

IV. CONCLUSION

While in different counts of their amended complaint appellants enlisted Section 21 and the APA as independent procedural vehicles, in each instance the end result they sought to achieve was initiation of a rulemaking proceeding for the purpose of considering adoption of a set of administrative actions which they proposed. [147] What, then, was before the District Court from the very beginning was an invocation of **[**46]** two separate remedies as means toward realization of a single objective. After they suffered an adverse ruling by the court on their APA approach, they chose to compromise and settle, in the course of their Section 21 effort, their substantive claims to relief. Now, having accomplished as much as they could by use of Section 21, appellants strive to better their lot by way of the APA. We discern nothing in the language, structure or legislative history of the Toxic Substances Control Act indicating that they should be indulged in so extraordinary an undertaking. We hold that appellants, having thus utilized Section 21, cannot now resort to any remedy that the APA might otherwise have afforded.

The judgment of the District Court is accordingly

Affirmed.

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[145] Brief for Appellants at 20. As the District Court stated, "because section 21 authorizes *de novo* review, neither the petitioners nor the agency are bound by the published reasons for denial. . . ." [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="] note 44, [HYPERLINK "https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4N-D7J0-003B-61VD-00000-00&context="].

[146] [HYPERLINK "https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSY1-NRF4-4217-00000-00&context="].

[147] We thus differentiate a claim to relief - the entitlement to a specific result -- from individual components of the claim, such as factual scenarios, grounds and reasons.

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 4/12/2019 9:45:08 AM
To: Baptist, Erik [Baptist.Erik@epa.gov]
Subject: Re: Follow Up

Will do Erik. Thank you.

LYNN L. BERGESON
MANAGING PARTNER
B E R G E S O N & C A M P B E L L P C
2200 Pennsylvania Avenue, N.W. Suite 100W |Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 lawbc.com

On Apr 12, 2019, at 5:41 AM, Baptist, Erik <Baptist.Erik@epa.gov> wrote:

Lynn,

Please submit the proposed modification to the consent order through the normal process. It will then go through the typical review and management chain. Please keep me apprised of your progress.

Thanks,

Erik Baptist
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson <lbergeson@lawbc.com>
Sent: Wednesday, April 10, 2019 7:54 PM
To: Baptist, Erik <Baptist.Erik@epa.gov>
Subject: Follow Up

Good evening Erik,

Our client is nearing a point of no return. Any update on this?

Thanks

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson
Sent: Friday, March 22, 2019 3:50 PM
To: Erik Baptist, Esquire

Cc: Richard E. Engler, Ph.D.
Subject: Follow Up

Hello Erik,

Rich and I spoke with you back in February (see below). When we spoke, we offered to suggest consent Order language to address the commercial reality of our client's (as well as other clients) need to distribute a PMN substance that has a invited a SNUR (but none has been issued in final) to its customer and its customer's need to distribute further the PMN substance, and the limitations in the Consent Order disallowing such further distribution. The appended suggests language to address this situation, while still providing EPA with the information it seeks to track the distribution of the substance. The PMN substance at issue here is P-17-0172.

We would be pleased to discuss.

Thanks

LYNN L. BERGESON
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From: Lynn L. Bergeson
Sent: Tuesday, February 12, 2019 8:55 AM
To: Erik Baptist, Esquire
Cc: Richard E. Engler, Ph.D.
Subject: Follow Up

Good Morning Erik,

We suspect EPA OPPT has received similar requests from others, but we wanted to run this scenario by you. We have a number of clients who have signed consent orders and are finding that the delay in promulgating final SNURs is a formidable barrier to the commercialization of the new chemical substances.

As you know, EPA consent orders allow distribution of a PMN substance to the submitter's direct customer provided the end-user agrees in writing to abide by the restrictions of the consent order and to not further distribute the PMN substance. The prohibition against further distribution automatically sunsets 75 days after the promulgation of a SNUR for the substance. The problem arises between the time when the consent order is signed and when the SNUR is published in final. An OPPT attorney-advisor has suggested that a submitter's customer's customer may submit a SNUN under 40 CFR Section 721.45(h) to allow the submitter's customer to distribute further a PMN substance once the SNUR is proposed but before it is published in final.

40 CFR §721.45 provides:

The persons identified in §721.5 are not subject to the notification requirements of §721.25 [SNUN requirements] for a chemical substance identified in subpart E [a specific SNUR] of this part, unless otherwise specified in a specific section in subpart E, if:

(h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in subpart E of this part which identifies the substance, and the person receives written notification of compliance from EPA prior to the effective date of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to part 720 of this chapter. For purposes of this exemption, the specific section in subpart E of this part which identifies the substance and §§721.1, 721.3, 721.11, 721.35, and 721.40 apply; after the effective date of the section in subpart E of this part which identifies the substance, §721.5 applies and §721.20 continues to apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:

1. EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances.
2. EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart E of this part which identifies the substance.

We would expect EPA to push back with a concern that the submitter (of the significant new use notice in this fact pattern) many not actually be engaging in a significant new use as envisioned in 721.45 (h), because the SNUN describes operating under the conditions specified in the consent order, and conclude this interpretation of 721.45(h) and the SNUN are invalid. In addition, EPA's approval of a SNUN submitted by the customer's customer would not change the prohibition in the consent order against further distribution. The customer's customer may be permitted to receive the substance as a result of EPA's action under 721.45(h), but the submitter's customer is still bound by the prohibition against further distribution. Conversely, if the submitter's customer submits a SNUN under 721.45(h), it is not clear how such a submission would bind the customer's customer.

We question whether 721. 45(h) allows the further distribution of a PMN substance as outlined above as suggested by the attorney-advisor. We recognize that even if this interpretation were deemed colorable, we would likely need OGC sign off.

Are we missing anything? Are there other options to permit distribution in supply chains that are more complex than just a manufacturer and direct customer, such as modifying consent orders to permit further distribution as long as written agreements are in place throughout the supply chain?

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Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 4/11/2019 3:29:59 PM
To: Baptist, Erik [Baptist.Erik@epa.gov]
Subject: Re: Follow Up

Thanks!!

LYNN L. BERGESON
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B E R G E S O N & C A M P B E L L P C
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On Apr 11, 2019, at 11:05 AM, Baptist, Erik <Baptist.Erik@epa.gov> wrote:

I'm planning to discuss with OPPT at our new chemicals meeting today.

Erik Baptist
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson <lbergeson@lawbc.com>
Sent: Wednesday, April 10, 2019 7:54 PM
To: Baptist, Erik <Baptist.Erik@epa.gov>
Subject: Follow Up

Good evening Erik,

Our client is nearing a point of no return. Any update on this?

Thanks

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From: Lynn L. Bergeson
Sent: Friday, March 22, 2019 3:50 PM
To: Erik Baptist, Esquire
Cc: Richard E. Engler, Ph.D.
Subject: Follow Up

Hello Erik,

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Sent: Tuesday, February 12, 2019 8:55 AM
To: Erik Baptist, Esquire
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Subject: Follow Up

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Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 4/10/2019 11:53:54 PM
To: Baptist, Erik [Baptist.Erik@epa.gov]
Subject: Follow Up
Attachments: 00264051.doc

Good evening Erik,

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Sent: Friday, March 22, 2019 3:50 PM
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(1) Notify in writing any person to who it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirement of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice must contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemistry identity.

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(2) Not further distribute the PMN substance to any other persons, other than for disposal, *unless* the Company obtains, in writing prior to the date of distribution, such person's agreement likewise to obtain a written agreement from any other recipient to whom the PMN substance is further distributed, that such recipient will comply with all requirements and restrictions set forth in this paragraph and will also obtain a written agreement from any additional recipients to comply with the requirements and restrictions in this paragraph. If at any time after commencing distribution of the PMN substance, the Company has knowledge that a person or recipient of the PMN substance is not complying with the requirements and restrictions of this paragraph, the Company will cease supplying

the PMN substance to such person, [unless the Company is able to document each of the following: (i) the Company has notified the person or recipient and EPA enforcement authorities, in writing within 15 working days of the time the Company develops knowledge that the person or recipient is not complying with the requirements and restrictions of this paragraph, that such person or recipient is not complying with the requirements and restrictions of this paragraph; (ii) that, within 15 working days of notifying the person or recipient as described in paragraph (b)(2)(i), the Company received from the person or recipient, in writing, a statement of assurance that the person or recipient is aware of and will comply with the requirements and restrictions of this paragraph; and (iii) that the Company has promptly provided EPA enforcement authorities with a copy of the person's or recepient's statement of assurance described in paragraph (b)(2)(ii). The copy must be sent to the Office of Enforcement and Compliance Assurance, Office of Compliance (2224A), U.S. Environmental Protection Agency, Ariel Rios, 1200 Pennsylvania Ave., N.W., Washington, DC 20044.]

Commented [A1]: This is part of 40 CFR 721.5. It might not cover all potential circumstances of non-compliance because this would be only when the Company obtains knowledge. Putting this requirement on anyone in the supply chain may prove too unwieldy but it could be considered. In addition, if the PMN submitter must cut off supply unless it can document downstream compliance, EPA may find more comfort that the PMN submitter has strong incentive to enforce its agreements (or risk the entire supply chain).

(3) Comply with the same requirements and restrictions, if any, required of the Company in the Protection of the Workplace section.

(4) Not process or use the PMN substance in any manner or method that generates mist, vapor, aerosol, or dust.

(c) Temporary Transport and Storage.

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 3/26/2019 3:21:03 PM
To: Baptist, Erik [Baptist.Erik@epa.gov]
Subject: RE: Follow Up

That is fine. Thanks. Appreciate all you are doing.

LYNN L. BERGESON
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From: Baptist, Erik [mailto:Baptist.Erik@epa.gov]
Sent: Tuesday, March 26, 2019 11:21 AM
To: Lynn L. Bergeson
Subject: RE: Follow Up

Yes, just a little overwhelmed at the moment. Is it time sensitive? I plan to review this week.

Erik Baptist
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson <lbergeson@lawbc.com>
Sent: Tuesday, March 26, 2019 8:55 AM
To: Baptist, Erik <Baptist.Erik@epa.gov>
Subject: FW: Follow Up

Hi Erik,

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LYNN L. BERGESON
MANAGING PARTNER
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Sent: Friday, March 22, 2019 3:50 PM
To: Erik Baptist, Esquire
Cc: Richard E. Engler, Ph.D.
Subject: Follow Up

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Message

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Sent: 3/26/2019 12:55:15 PM
To: Baptist, Erik [Baptist.Erik@epa.gov]
Subject: FW: Follow Up
Attachments: 00264051.doc

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(1) Notify in writing any person to who it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirement of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice must contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemistry identity.

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(2) Not further distribute the PMN substance to any other persons, other than for disposal, *unless* the Company obtains, in writing prior to the date of distribution, such person's agreement likewise to obtain a written agreement from any other recipient to whom the PMN substance is further distributed, that such recipient will comply with all requirements and restrictions set forth in this paragraph and will also obtain a written agreement from any additional recipients to comply with the requirements and restrictions in this paragraph. If at any time after commencing distribution of the PMN substance, the Company has knowledge that a person or recipient of the PMN substance is not complying with the requirements and restrictions of this paragraph, the Company will cease supplying

the PMN substance to such person, [unless the Company is able to document each of the following: (i) the Company has notified the person or recipient and EPA enforcement authorities, in writing within 15 working days of the time the Company develops knowledge that the person or recipient is not complying with the requirements and restrictions of this paragraph, that such person or recipient is not complying with the requirements and restrictions of this paragraph; (ii) that, within 15 working days of notifying the person or recipient as described in paragraph (b)(2)(i), the Company received from the person or recipient, in writing, a statement of assurance that the person or recipient is aware of and will comply with the requirements and restrictions of this paragraph; and (iii) that the Company has promptly provided EPA enforcement authorities with a copy of the person's or recepient's statement of assurance described in paragraph (b)(2)(ii). The copy must be sent to the Office of Enforcement and Compliance Assurance, Office of Compliance (2224A), U.S. Environmental Protection Agency, Ariel Rios, 1200 Pennsylvania Ave., N.W., Washington, DC 20044.]

Commented [A1]: This is part of 40 CFR 721.5. It might not cover all potential circumstances of non-compliance because this would be only when the Company obtains knowledge. Putting this requirement on anyone in the supply chain may prove too unwieldy but it could be considered. In addition, if the PMN submitter must cut off supply unless it can document downstream compliance, EPA may find more comfort that the PMN submitter has strong incentive to enforce its agreements (or risk the entire supply chain).

(3) Comply with the same requirements and restrictions, if any, required of the Company in the Protection of the Workplace section.

(4) Not process or use the PMN substance in any manner or method that generates mist, vapor, aerosol, or dust.

(c) Temporary Transport and Storage.

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 3/22/2019 7:50:27 PM
To: Baptist, Erik [Baptist.Erik@epa.gov]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: Follow Up
Attachments: 00264051.doc

Hello Erik,

Rich and I spoke with you back in February (see below). When we spoke, we offered to suggest consent Order language to address the commercial reality of our client's (as well as other clients) need to distribute a PMN substance that has a invited a SNUR (but none has been issued in final) to its customer and its customer's need to distribute further the PMN substance, and the limitations in the Consent Order disallowing such further distribution. The appended suggests language to address this situation, while still providing EPA with the information it seeks to track the distribution of the substance. The PMN substance at issue here is P-17-0172.

We would be pleased to discuss.

Thanks

LYNN L. BERGESON
MANAGING PARTNER
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2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

---

From: Lynn L. Bergeson
Sent: Tuesday, February 12, 2019 8:55 AM
To: Erik Baptist, Esquire
Cc: Richard E. Engler, Ph.D.
Subject: Follow Up

Good Morning Erik,

We suspect EPA OPPT has received similar requests from others, but we wanted to run this scenario by you. We have a number of clients who have signed consent orders and are finding that the delay in promulgating final SNURs is a formidable barrier to the commercialization of the new chemical substances.

As you know, EPA consent orders allow distribution of a PMN substance to the submitter's direct customer provided the end-user agrees in writing to abide by the restrictions of the consent order and to not further distribute the PMN substance. The prohibition against further distribution automatically sunsets 75 days after the promulgation of a SNUR for the substance. The problem arises between the time when the consent order is signed and when the SNUR is published in final. An OPPT attorney-advisor has suggested that a submitter's customer's customer may submit a SNUN under 40 CFR Section 721.45(h) to allow the submitter's customer to distribute further a PMN substance once the SNUR is proposed but before it is published in final.

40 CFR §721.45 provides:

The persons identified in §721.5 are not subject to the notification requirements of §721.25 [SNUN requirements] for a chemical substance identified in subpart E [a specific SNUR] of this part, unless otherwise specified in a specific section in subpart E, if:

(h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in subpart E of this part which identifies the substance, and the person receives written notification of compliance from EPA prior to the effective date of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to part 720 of this chapter. For purposes of this exemption, the specific section in subpart E of this part which identifies the substance and §§721.1, 721.3, 721.11, 721.35, and 721.40 apply; after the effective date of the section in subpart E of this part which identifies the substance, §721.5 applies and §721.20 continues to apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:

1. EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances.
2. EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart E of this part which identifies the substance.

We would expect EPA to push back with a concern that the submitter (of the significant new use notice in this fact pattern) many not actually be engaging in a significant new use as envisioned in 721.45 (h), because the SNUN describes operating under the conditions specified in the consent order, and conclude this interpretation of 721.45(h) and the SNUN are invalid. In addition, EPA's approval of a SNUN submitted by the customer's customer would not change the prohibition in the consent order against further distribution. The customer's customer may be permitted to receive the substance as a result of EPA's action under 721.45(h), but the submitter's customer is still bound by the prohibition against further distribution. Conversely, if the submitter's customer submits a SNUN under 721.45(h), it is not clear how such a submission would bind the customer's customer.

We question whether 721. 45(h) allows the further distribution of a PMN substance as outlined above as suggested by the attorney-advisor. We recognize that even if this interpretation were deemed colorable, we would likely need OGC sign off.

Are we missing anything? Are there other options to permit distribution in supply chains that are more complex than just a manufacturer and direct customer, such as modifying consent orders to permit further distribution as long as written agreements are in place throughout the supply chain?

We would be happy to discuss. We suspect we are not alone in seeking guidance on this issue as supply chains today are more complicated than the "single distribution" language contemplates.

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(b) Distribution Requirements. Except as provided in paragraph (c), and except for end users who will conduct no further processing of the PMN substance, the Company is permitted to distribute the PMN substance outside the Company, other than for disposal, only to a persons who haves agreed in writing prior to the date of distribution, to:

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(1) Notify in writing any person to who it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirement of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice must contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemistry identity.

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(2) Not further distribute the PMN substance to any other persons, other than for disposal, *unless* the Company obtains, in writing prior to the date of distribution, such person's agreement likewise to obtain a written agreement from any other recipient to whom the PMN substance is further distributed, that such recipient will comply with all requirements and restrictions set forth in this paragraph and will also obtain a written agreement from any additional recipients to comply with the requirements and restrictions in this paragraph. If at any time after commencing distribution of the PMN substance, the Company has knowledge that a person or recipient of the PMN substance is not complying with the requirements and restrictions of this paragraph, the Company will cease supplying

the PMN substance to such person, [unless the Company is able to document each of the following: (i) the Company has notified the person or recipient and EPA enforcement authorities, in writing within 15 working days of the time the Company develops knowledge that the person or recipient is not complying with the requirements and restrictions of this paragraph, that such person or recipient is not complying with the requirements and restrictions of this paragraph; (ii) that, within 15 working days of notifying the person or recipient as described in paragraph (b)(2)(i), the Company received from the person or recipient, in writing, a statement of assurance that the person or recipient is aware of and will comply with the requirements and restrictions of this paragraph; and (iii) that the Company has promptly provided EPA enforcement authorities with a copy of the person's or recepient's statement of assurance described in paragraph (b)(2)(ii). The copy must be sent to the Office of Enforcement and Compliance Assurance, Office of Compliance (2224A), U.S. Environmental Protection Agency, Ariel Rios, 1200 Pennsylvania Ave., N.W., Washington, DC 20044.]

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(4) Not process or use the PMN substance in any manner or method that generates mist, vapor, aerosol, or dust.

(c) Temporary Transport and Storage.

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 2/28/2019 11:40:22 AM
To: Baptist, Erik [Baptist.Erik@epa.gov]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: Re: Follow Up

Will do

LYNN L. BERGESON
MANAGING PARTNER
B E R G E S O N & C A M P B E L L P C
2200 Pennsylvania Avenue, N.W. Suite 100W |Washington, D.C. 20037
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On Feb 28, 2019, at 6:38 AM, Baptist, Erik <Baptist.Erik@epa.gov> wrote:

Yes please.

Erik Baptist
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson <lbergeson@lawbc.com>
Sent: Thursday, February 28, 2019 6:33 AM
To: Baptist, Erik <Baptist.Erik@epa.gov>
Cc: Richard E. Engler, Ph.D. <rengler@lawbc.com>
Subject: RE: Follow Up

Ok. Call your office?

LYNN L. BERGESON
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From: Baptist, Erik [mailto:Baptist.Erik@epa.gov]
Sent: Thursday, February 28, 2019 6:27 AM
To: Lynn L. Bergeson
Cc: Richard E. Engler, Ph.D.
Subject: RE: Follow Up

Great – let's plan for 2:30.

Erik Baptist
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson <lbergeson@lawbc.com>
Sent: Thursday, February 28, 2019 6:25 AM
To: Baptist, Erik <Baptist.Erik@epa.gov>
Cc: Richard E. Engler, Ph.D. <rengler@lawbc.com>
Subject: RE: Follow Up

Sure, I am free after 2:30. Thanks

LYNN L. BERGESON
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From: Baptist, Erik [mailto:Baptist.Erik@epa.gov]
Sent: Thursday, February 28, 2019 6:24 AM
To: Lynn L. Bergeson
Cc: Richard E. Engler, Ph.D.
Subject: RE: Follow Up

Let's plan to discuss tomorrow afternoon, if that works for you.

Erik Baptist
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
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baptist.erik@epa.gov

From: Lynn L. Bergeson <lbergeson@lawbc.com>
Sent: Wednesday, February 27, 2019 5:53 AM
To: Baptist, Erik <Baptist.Erik@epa.gov>
Cc: Richard E. Engler, Ph.D. <rengler@lawbc.com>
Subject: Follow Up

Erik,

Would you have any opportunity to discuss this any time soon?

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From: Lynn L. Bergeson
Sent: Tuesday, February 12, 2019 8:55 AM

To: Erik Baptist, Esquire
Cc: Richard E. Engler, Ph.D.
Subject: Follow Up

Good Morning Erik,

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Thanks

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T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 2/28/2019 11:32:58 AM
To: Baptist, Erik [Baptist.Erik@epa.gov]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: RE: Follow Up

Ok. Call your office?

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Sent: Thursday, February 28, 2019 6:27 AM
To: Lynn L. Bergeson
Cc: Richard E. Engler, Ph.D.
Subject: RE: Follow Up

Great – let's plan for 2:30.

Erik Baptist
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
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Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson <lbergeson@lawbc.com>
Sent: Thursday, February 28, 2019 6:25 AM
To: Baptist, Erik <Baptist.Erik@epa.gov>
Cc: Richard E. Engler, Ph.D. <rengler@lawbc.com>
Subject: RE: Follow Up

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To: Lynn L. Bergeson
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To: Erik Baptist, Esquire
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Subject: Follow Up

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Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 2/28/2019 11:25:24 AM
To: Baptist, Erik [Baptist.Erik@epa.gov]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: RE: Follow Up

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Sent: Thursday, February 28, 2019 6:24 AM
To: Lynn L. Bergeson
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Subject: RE: Follow Up

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40 CFR §721.45 provides:

The persons identified in §721.5 are not subject to the notification requirements of §721.25 [SNUN requirements] for a chemical substance identified in subpart E [a specific SNUR] of this part, unless otherwise specified in a specific section in subpart E, if:

(h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in subpart E of this part which identifies the substance, and the person receives written notification of compliance from EPA prior to the effective date of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to part 720 of this chapter. For purposes of this exemption, the specific section in subpart E of this part which identifies the substance and §§721.1, 721.3, 721.11, 721.35, and 721.40 apply; after the effective date of the section in subpart E of this part which identifies the substance, §721.5 applies and §721.20 continues to apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:

1. EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances.
2. EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart E of this part which identifies the substance.

We would expect EPA to push back with a concern that the submitter (of the significant new use notice in this fact pattern) many not actually be engaging in a significant new use as envisioned in 721.45 (h), because the SNUN describes operating under the conditions specified in the consent order, and conclude this interpretation of 721.45(h) and the SNUN are invalid. In addition, EPA's approval of a SNUN submitted by the customer's customer would not change the prohibition in the consent order against further distribution. The customer's customer may be permitted to receive the substance as a result of EPA's action under 721.45(h), but the submitter's customer is still bound by the prohibition against further distribution. Conversely, if the submitter's customer submits a SNUN under 721.45(h), it is not clear how such a submission would bind the customer's customer.

We question whether 721. 45(h) allows the further distribution of a PMN substance as outlined above as suggested by the attorney-advisor. We recognize that even if this interpretation were deemed colorable, we would likely need OGC sign off.

Are we missing anything? Are there other options to permit distribution in supply chains that are more complex than just a manufacturer and direct customer, such as modifying consent orders to permit further distribution as long as written agreements are in place throughout the supply chain?

We would be happy to discuss. We suspect we are not alone in seeking guidance on this issue as supply chains today are more complicated than the "single distribution" language contemplates.

Thanks

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
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Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 2/27/2019 10:52:48 AM
To: Baptist, Erik [Baptist.Erik@epa.gov]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: Follow Up

Erik,

Would you have any opportunity to discuss this any time soon?

LYNN L. BERGESON
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From: Lynn L. Bergeson
Sent: Tuesday, February 12, 2019 8:55 AM
To: Erik Baptist, Esquire
Cc: Richard E. Engler, Ph.D.
Subject: Follow Up

Good Morning Erik,

We suspect EPA OPPT has received similar requests from others, but we wanted to run this scenario by you. We have a number of clients who have signed consent orders and are finding that the delay in promulgating final SNURs is a formidable barrier to the commercialization of the new chemical substances.

As you know, EPA consent orders allow distribution of a PMN substance to the submitter's direct customer provided the end-user agrees in writing to abide by the restrictions of the consent order and to not further distribute the PMN substance. The prohibition against further distribution automatically sunsets 75 days after the promulgation of a SNUR for the substance. The problem arises between the time when the consent order is signed and when the SNUR is published in final. An OPPT attorney-advisor has suggested that a submitter's customer's customer may submit a SNUN under 40 CFR Section 721.45(h) to allow the submitter's customer to distribute further a PMN substance once the SNUR is proposed but before it is published in final.

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Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 2/12/2019 1:55:05 PM
To: Baptist, Erik [Baptist.Erik@epa.gov]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: Follow Up

Good Morning Erik,

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Message

From: Chad H. Howlin [chowlin@lawbc.com]
Sent: 7/18/2018 12:06:46 AM
To: Morris, Jeff [Morris.Jeff@epa.gov]
CC: lbergeson@lawbc.com; Richard E. Engler, Ph.D. [rengler@lawbc.com]; Kathleen M. Roberts [kroberts@bc-cm.com]; Lawrence D. Sloan [lsloan@aiha.org]; Mark Ames [mames@aiha.org]; Baptist, Erik [Baptist.Erik@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]; 'Blunk.chris@Epa.gov' [Blunk.chris@Epa.gov]; Nguyen, Nhan [Nguyen.Nhan@epa.gov]
Subject: AIHA/EPA Meeting
Attachments: 00246914.pdf

Appended is a letter regarding the meeting on July 12, 2018.

Thanks.

CHAD H. HOWLIN
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BERGESON&CAMPBELL PC

July 17, 2018

Via E-Mail

Jeffery Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Jeff:

Thanks to you and your staff for visiting with Larry Sloan, Chief Executive Officer, American Industrial Hygiene Association (AIHA), and Mark Ames, AIHA Director, Government Relations, and my colleagues on Thursday, July 12, 2018. Our hope in meeting was to facilitate closer collaboration between the U.S. Environmental Protection Agency (EPA) and AIHA on issues relating to worker health and safety.

As Larry noted, AIHA is one of the world's largest international associations serving occupational and environmental health and safety professionals practicing industrial hygiene. AIHA offers an impressive array of educational and related resources for its members, and it wishes to collaborate more with EPA's Office of Pollution Prevention and Toxics (OPPT) in addressing workplace exposure issues on which EPA is directed to consult with the U.S. Occupational Safety and Health Administration (OSHA) under Section 5(f)(5) of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

When we met, EPA asked for additional information on several topics: the process companies follow in drafting a Safety Data Sheet (SDS) for new chemicals, particularly with respect to worker protection measures and specifically hand protection, and information on the "best in class" training that SDS authors must obtain to sit for the AIHA SDS Label Authoring Registry Competency Assessment. We have coordinated with AIHA and are pleased to assist in providing this information.

As we discussed, chemical manufacturers have significant experience in developing protective measures for employees and others who may be exposed to their new chemical innovations. These measures are routinely included in SDSs. The chemical industry has achieved, over the course of many decades, a high standard of worker health and safety well beyond enforceable health and safety standards required under federal law. The success of these industry standards is reflected in metrics we discussed at our meeting. As noted, we reviewed OSHA violation records dated from March 15, 1972, to June 22, 2018, relating to several

categories of personal protective clothing and equipment including general clothing protection, eye protection, respiratory protection, and hand protection. Hand protection accounted for 0.077% of the total number of violations, an incredibly small percentage. https://enfxfr.dol.gov/data_catalog/OSHA/osha_inspection_20180712.csv.zip. This statistical breakdown is appended as Attachment A.

Further evidence of the success of these industry standards is found in the number of OSHA incident reports submitted from 1972 to June of 2018. Again, focusing on chemical accidents involving hand injury, a total of 13 incidents were reported as 0.01069721% of the total. https://enforcedata.dol.gov/views/data_summary.php. After accessing this website, you must then select "OSHA Enforcement Data." This statistical breakdown is appended as Attachment B.

EPA asked for more information on how chemical innovators prepare SDSs for new chemicals. As EPA knows well, there is a robust universe of guidance documents, standards, and how-tos to assist companies in developing SDSs. OSHA's Personal Protective Equipment (PPE) Guide makes clear that the nature of the hazard and the operation involved are critically important in the selection of gloves. The ANSI standard, ANSI/ISEA 105-2016 addresses the classification and testing of hand protection for specific performance properties related to chemical and industrial applications. This standard provides performance ranges related to mechanical protection (cut-resistance, puncture resistance, and abrasion resistance), chemical protection (permeation resistance, degradation), and other performance characteristics such as ignition resistance and vibration reductions based on standardized test methods. The ASTM standard, which EPA refers to in its consent orders, measures the permeation of liquids and gases through protective clothing materials under the condition of continuous contact. Finally, we note that glove manufacturers often develop their own specifications, which EPA also includes in consent orders as an alternative to the ASTM standard. It is our understanding that EPA evaluates specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the premanufacture notice (PMN) substances alone and in likely combination with other chemical substances in the work area. We append as Attachment C a detailed listing of other helpful and readily available standards and guidance documents that are used extensively in the chemical sector in preparing SDSs.

As a follow-up to EPA's specific question relating to the SDS Author Registry, we append three documents at Attachment D that EPA may find useful in explaining what skills an SDS author needs to master to pass the AIHA SDS Author Registry exam.

Finally, we wanted to share information on the Center for Safety & Health Sustainability (CSHS). We append at Attachment E a CSHS tri-fold, a CSHS white paper on

sustainability reporting, and an OSHA white paper on sustainability reporting. As discussed at our meeting, CSHS commissioned Harvard Law School last year to conduct a "Human Capital" project that reviewed publicly reported occupational environmental health and safety (EHS) metrics across multi-national companies to gain a better sense of who is doing what. Much work needs to be done in the area of harmonizing metrics globally, as well as defining leading metrics vs. conventional lag. If EPA is interested in learning more about CSHS, AIHA would be pleased to arrange a separate meeting with Alan Leibowitz, who serves on the CSHS' Board of Directors, and Russ Hayward, AIHA's resident CIH and managing Director, Scientific and Technical Initiatives, who serves as AIHA's primary staff point of contact for CSHS.

As discussed during our meeting, AIHA and Bergeson & Campbell, P.C. are interested in assisting EPA and the other federal agencies with which EPA meets monthly to consider issues of cross-agency interest, OSHA, the Mine Safety and Health Administration (MSHA), and the National Institute of Occupational Safety and Health (NIOSH) as the interagency OMNE Committee. We would welcome an opportunity to provide additional resources and perspectives to assist the Committee's deliberations.

Sincerely,

Lynn L. Bergeson

Attachments:
A -- OSHA Standard Violations
B -- OSHA Accident Records
C -- PPE – A Brief Overview of Gloves Standards
D -- AIHA SDS Author Registry
E -- CSHS Tri-fold, CSHS White Paper, and OSHA White Paper

Attachment A

OSHA violation records dated March 15, 1972 to June 22, 2018

	29 CFR	Number of violations	Percentage of all violations	Comment
General clothing protection	1910.132(h)(4)(iii)	1	0.000008%	Long sleeves, long pants, proper shoes
Eye protection	1910.133(a)(1)	50,784	0.418%	Goggles, face shield, etc. Includes flying particles, liquid chemicals, gases, vapors or injurious light radiation
Respiratory Protection	1910.134(a)(2)	24,426	0.201%	Respirators which are applicable and suitable for the purpose intended
Hand protection (general)	1910.138	9,338	0.077%	Includes both glove non-use (a) and wrong type (b)
All violations		12,148,585		

Source: https://enfxfr.dol.gov/data_catalog/OSHA/osha_violation_20180706.csv.zip
Violations exclude 136 records that lead to database import errors.

Attachment B

OSHA accident records from 1972-2018

	Number of accidents	Percentage of all accidents	Comment
All accidents involving the chemical industry from 1972-2018	2,044	1.68193076%	Any accidents in the chemical industry
Accidents involving chemicals in the chemical industry from 1972-2018	393	0.32338493%	Excluded accidents with physical trauma
Chemical accidents involving hands in the chemical industry (including explosions and fire) from 1972-2018	13	0.01069721%	Any chemical accidents where hands were injured
Chemical accidents involving hands (when excluded explosions and fire) in the chemical industry from 1972-2018	1	0.00082286%	9/3/1993; Employee dies from agrochemical absorption; event keywords: PPE,GLOVE,WORK RULES, HAND, CHEMICAL.
Chemical accidents involving dermal contact in the chemical industry from 1972-2018	17	0.01398866%	Any type of dermal exposure
All violations	121,527		

Source: https://enforcedata.dol.gov/views/data_summary.php
Violations exclude 2616 records with multiple SIC
Search queries based on SIC 28xx and 29xx (chemical industry and petroleum refinery industry)

Attachment C

Personal Protective Equipment – A Brief Overview of Gloves Standards

American National Standards Institute (ANSI)

ANSI/ISEA 105-2016 American National Standard for Hand Protection Classification: The document classifies a whole glove or material used in the construction of an occupational glove to help people understand glove performance data if they are not familiar with the details of the test methods and the results to be expected when testing. This document provides or refers to appropriate test methods for specified criteria and provides pass/fail criteria to allow users to interpret test results and determine if certain hand protection products meet their needs.
Official Document

Hazard Protection

Hazards: Cut-resistance, puncture resistance (other than hypodermic needle), hypodermic needle puncture resistance, abrasion resistance, chemical permeation resistance, chemical degradation resistance, heat and flame protection, ignition resistance and burning resistance, heat degradation resistance, conducive heat resistance, vibration reduction, dexterity.

The standard does not address protection from electric shock, ionizing or non-ionizing radiation, every type of thermal exposure and harmful temperature extreme, and every type of exposure to chemicals, biological agents, or other hazardous substances. This standard does not address protection for welding, emergency response applications or fire fighter applications.

Test Methods

Cut resistance: ASTM F2992-15. Cut resistance testing measures how the glove material will resist cutting by a sharp edge. Larger weights reported by this test method indicate a glove material with greater cut resistance.

Puncture resistance (other than hypodermic needle): EN 388:2003. Puncture resistance testing measures how the glove material will resist puncture by a pointed object. Higher puncture forces reported by this test method indicate a glove with greater puncture resistance.

Hypodermic needle puncture resistance: ASTM F2878-10. Puncture resistance testing measures how the glove material will resist puncture by a sharp-edged needle. Higher puncture forces reported by this test method indicate a glove with greater puncture resistance.

Abrasion resistance: ASTM D3389-10 and ASTM D3884-09. Abrasion resistance testing measures how the well the glove material resists loss of material from rubbing on rough surfaces. Larger numbers of abrasion cycles until failure reported by this method indicate a glove with greater abrasion resistance.

Chemical permeation resistance: ASTM F739-12. Permeation resistance testing measures the rate at which chemicals (contacting the glove) pass through glove materials on a molecular level.

Longer breakthrough times indicate materials with better chemical permeation resistance. Permeation rates may be used to determine how much chemical passes through the material in a given period.

Chemical degradation resistance: Appendix B in standard. Degradation resistance testing measures the effects of a chemical on a glove material. In this test, the measured effect is loss of puncture resistance. Lower percentage changes in puncture resistance indicate gloves with greater chemical degradation resistance.

Ignition resistance and burning behavior (or after-flame time): ASTM F1358-08. Ignition resistance and burning behavior testing measures how easily a glove material will ignite and if ignited how readily the material will continue to burn once the flame is removed. Materials that show no ignition or longer ignition times and short after-burn times (time for the burning material to extinguish following removal of the flame) using this method are considered to perform better when exposed to a flame for a short time.

Heat degradation resistance: ISO 17493:2000. Heat degradation testing determines the exposure temperature at which gloves will be thermally stable (*i.e.*, show no significant heat degradation). Higher temperatures reported by this method indicate gloves having greater heat degradation resistance.

Conductive heat resistance: ASTM F1060-08. Conductive heat resistance testing measures the insulation provided by the glove when in contact with a hot surface. Higher temperatures reported by this method indicate gloves with greater insulation for contact with hot surfaces.

Vibration resistance: ANSI S2.73-2002 (R2007). This measures the vibration transmissibility of the glove by comparing the difference between the two sites across a spectrum of frequencies.

Dexterity: EN 430:2009. Dexterity is the ability of the wearer to manipulate objects and control his hands in the desired manner. In this case, it is assessed by determining the wearer's ability to pick up between his thumb and forefinger small diameter pins lying on a flat surface. The dexterity of the glove is highest when the wearer can pick up the smallest diameter pin provided.

Other factors

Natural Rubber Latex: Workers exposed to natural rubber latex as a component of gloves may develop allergic reactions. Latex gloves have proved effective in preventing transmission of many infectious diseases to healthcare workers. Some people exposed to latex develop allergic reactions in the form of rash, hives, itching and other symptoms. The medical community has not established safe levels of proteins to evaluate latex-containing products.

Viral Penetration Resistance: The penetration of viruses or other biological agents may be a concern for hand protection products that do not use continuous barriers or products using microporous films. Viral penetration resistance testing measures the effectiveness of whole gloves or glove materials in preventing the transmission of a bacteriophage, or viral simulant for Hepatitis and Human Immunodeficiency Viruses.

Chemical Penetration: In some work environment, chemical permeation resistance may represent a severe exposure to gloves not mimicked by all types of chemical exposures. For some exposures involving low hazard liquids, acceptable performance can be demonstrated by resistance to penetration.

Human Factors: Human factors relate to the fit, function, and comfort provided by gloves. The protection provided by gloves against specific hazards typically involves some tradeoff with hand comfort and functionality. These properties are generally subjective and will depend on the perception of the wearer, the type of work being performed, the environmental conditions, and the length of the wearing period.

Fit: Gloves should fit properly. The relative fit of the gloves may be a function of the particular glove design, available sizes for a particular glove style, and the personal preferences of the wearer for fit. Manufacturers provide numerical sizes (*e.g.*, size 9) for some styles and size descriptions (*e.g.*, small) for other styles. Some manufacturers provide sizing charts or indicate how to measure hands to select the appropriate sized glove based on their sizing system.

Function: Glove function is most often characterized in terms of dexterity, tactility, and grip. Criteria for dexterity are incorporated in ANSI/ISEA 105-2016. There are no standard tests for tactility. Often tactility is measured by how well a person can identify objects by touch without looking at the objects. Grip is affected by the type of treatment on the glove surface, the type of object being grasped and the presence of any wetness or other substances. Good grip in gloves allows the wear to hold heavy objects in different orientations.

DIN EN 420:2010: Protective gloves -- General requirements and test methods; German version EN 420:2003+A1:2009 (Foreign Standard): This standard defines the general requirements and relevant test procedures for glove design and construction, resistance of glove materials to water penetration, innocuousness, comfort and efficiency, marking and information supplied by the manufacturer applicable to all protective gloves. NOTE It can also be applicable to arm protectors and gloves permanently incorporated in containment enclosures. This European Standard does not address the protective properties of gloves and therefore should not be used alone but only in combination with the appropriate specific European Standard(s).
Official Document

American Society for Testing and Materials (ASTM International)

ASTM F739 -- 12e1: Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact: The document provides definitive test method which measures the permeation of liquids and gases through protective clothing materials under the condition of continuous contact. This test method is designed for use when the test chemical is a gas or a liquid, where the liquid is either volatile (that is, having a vapor pressure greater than 1 mm Hg at 25°C) or soluble in water or another liquid that does not interact with the clothing material.
Official Document

ASTM F1383 - 12e1: Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Intermittent Contact: The document provides definitive test method which measures the permeation of liquids and gases through protective clothing materials under the condition of intermittent contact. This test method is designed for use when the test chemical is a gas or a liquid, where the liquid is either volatile (that is, having a vapor pressure greater than 1 mm Hg at 25°C) or soluble in water or another liquid that does not interact with the clothing material.
Official Document

ASTM F903 – 18: Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Liquids: The document provides definitive test method which is used to test specimens of protective clothing materials, assemblies such as seams and closures, or interfaces used in the construction of protective clothing. The resistance to visible penetration of the test liquid is determined with the liquid in continuous contact with the normally outside (exterior) surface of the test specimen. This test method includes different procedures for maintaining the liquid in contact with the test specimen in terms of the length of exposure and the pressure applied. Suggestions are provided for how to select an appropriate procedure for liquid contact. In some cases, significant amounts of hazardous materials will permeate specimens that pass the penetration tests. For more sensitive analyses, use either Test Method F739 or F1383 to determine permeation. This test method does not address penetration of vapors through protective clothing materials. **This test method is not applicable to** non-planar protective clothing materials, interfaces, or **assemblies such as the fingertips or crotch areas of gloves**, which are possible failure points.
Official Document

ASTM F1461 -- 17: Standard Practice for Chemical Protective Clothing Program: This practice is intended to promote the proper selection, use, maintenance, and understanding of the limitations of chemical protective clothing (CPC) by users, employers, employees, and other persons involved in programs requiring CPC, thereby limiting potentially harmful and unnecessary skin exposures.
Official Document

ASTM F1296 - 08(2015): Standard Guide for Evaluating Chemical Protective Clothing: This guide is intended to aid in the application of standards for the development, specification, and selection of chemical protective clothing with the ultimate goal of maintaining the safety and health of workers who come into contact with hazardous chemicals. This guide provides a short description of each referenced standard and then makes specific recommendations for the use of these standards. The referenced standards are organized under the following headings: Material Chemical Resistance, Material Physical Properties, Seam and Closure Performance, and Overall Clothing Performance. No protocol can ensure the selection of protective clothing that guarantees worker protection. The purpose of testing is to generate data and information that will allow the selection of the most appropriate clothing. Ultimately, clothing selection is based on technical evaluation of available information and professional assessment of risk.
Official Document

International Organization for Standardization (ISO)

ISO/DIS 21420: Protective gloves -- General requirements and test method: This standard defines the general requirements and relevant test procedures for glove design and construction, resistance of glove materials to water penetration, innocuousness, comfort and efficiency, marking and information supplied by the manufacturer applicable to all protective gloves.
Official Document

ISO 6529:2013: Protective clothing -- Protection against chemicals -- Determination of resistance of protective clothing materials to permeation by liquids and gases: ISO 6529:2013 describes laboratory test methods to determine the resistance of materials used in protective clothing, including gloves and including footwear, when the footwear is an integral part of the clothing, to permeation by liquid or gaseous chemicals under the conditions of either continuous or intermittent contact.

Method A is applicable to testing against liquid chemicals, either volatile or soluble in water, expected to be in continuous contact with the protective clothing material.

Method B is applicable to testing against gaseous chemicals expected to be in continuous contact with the protective clothing material.

Method C is applicable to testing against gaseous and liquid chemicals, either volatile or soluble in water, expected to be in intermittent contact with the protective clothing material.

These test methods assess the permeation resistance of the protective clothing material under laboratory conditions in terms of breakthrough time, permeation rate, and cumulative permeation. These test methods also enable qualitative observations to be made of the effects of the test chemical on the material under test.

These test methods are only suitable for measuring permeation by liquids and gases.

These test methods address only the performance of materials or certain materials' constructions (*e.g.*, seams).
Official Document

Standards Catalogue -- 13.340.40 -- Hand and arm protection (Including protective gloves, sleeves and mits): This catalogue included all of ISO standards for hand and arm protections.
Official Catalogue

Center for Disease Control and Prevention (CDC)

The National Institute for Occupational Safety and Health (NIOSH) -- Recommendations for Chemical Protective Clothing Database: This report provides CPC recommendations for the chemicals listed in the *NIOSH Pocket Guide to Chemical Hazards, June 1997 Edition* (Publication No. 97-140). These recommendations are based on another published work, *Quick Selection Guide to Chemical Protective Clothing, Third Edition*, by Krister Forsberg and S.Z. Mansdorf (1997).
Official Database

The National Institute for Occupational Safety and Health (NIOSH) -- A Guide for Evaluating the Performance of Chemical Protective Clothing: This guide describes a method for an industrial hygienist or equivalent safety professional to select appropriate CPC. The steps in the selection process are: (1) evaluating the workplace, (2) obtaining samples of candidate CPC, (3) testing the samples under the conditions in which they will be used, and (4) selecting the best candidate protective clothing. These steps are discussed, and an example is given for using the selection process.
Official Guide

NIOSH Personal Protective Equipment Information (PPE-Info): The PPE-Info Database serves as a compendium of federal regulations and consensus standards for Personal Protective Equipment (PPE). Standards information was compiled from the U.S. Government, American National Standards Institute (ANSI) accredited standard development organizations (SDO), and International Organization for Standardization (ISO), when applicable nationally. Please note that there are 28 OSHA-approved occupational safety and health State Plans. State Plans are required to have standards and enforcement programs that are at least as effective as federal OSHA's and may have different or more stringent standards related to PPE. More information about State Plans and their standards is available at: https://www.osha.gov/dcsp/osp/index.html. The purpose of the database is to provide standards developers, manufacturers, purchasers, and end users of PPE with a comprehensive tool which allows general or advanced criteria searches of relevant federal standards, associated product types, target occupational groups, basic conformity assessment specifications, and accredited lab information.
Official Database

Occupational Safety and Health Administration (OSHA)

Personal Protective Equipment: This publication provides a general overview of personal protective equipment (PPE). This guide will help both employers and employees to (1) understand the types of PPE; (2) know the basics of conducting a "hazard assessment" of the workplace; (3) select appropriate PPE for a variety of circumstances; and (4) understand what kind of training is needed in the proper use and care of PPE. On pages 22-29 there is a guide to hand and arm protection.
Official Guide

Assessing the Need for Personal Protective Equipment: A Guide for Small Business Employers: This publication provides guidance for small business employers to provide appropriate PPE for their employees. The guide addresses the following: (1) examination of the workplace; (2) review of the work procedures requirements; (3) selection of appropriate PPE (except for respirators and insulation rubber equipment) to protect the employee; and (4) employee training on how to wear and care for the PPE.
Official Guide

(Canada) Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST)

Protective Gloves Selection Guide: This protective gloves selection guide includes an interactive selection tool and a **PDF information document**. The objective of this guide is to provide necessary information for helping individuals and Occupational Health and Safety (OH&S) managers identify protective gloves that correspond to their needs. The interactive selection tool allows a search of information on a specific glove model as well as a criteria-based search for glove models, in particular according to the resistance to mechanical risks, food handling compliance, and cost. The PDF information document provides information on relevant laws and regulations, risk management process, types of gloves, manufacturing processes, materials, and risks and characterization methods among others. It includes also some examples of situation scenarios.
Official Database

Office of Environment, Health & Safety, University of California, Berkeley

Glove Selection Guide (Focused on laboratory staff): This checklist is used to choose the appropriate type of protective glove for the job. A step-by-step guide is available to evaluate work setting, hazardous materials, duration of contact, and disposal methods. A glove comparison chart is also available as an overview of commonly used glove types for laboratory use and their general advantages and disadvantages.
Official Guide

ChemRest -- Showa Group

Chemical Resistant Glove Database: This database allows users to search for chemical resistant gloves using the chemical Chemical Abstracts Service (CAS) number or chemical name. The user can also search for gloves using the product name or model number. The user guide is available here.
Official Database

Ansell

Ansell SpecWare online chemical hand protection -- Chemical Application and Recommendation Guide (ASTM Standard): This database allows users to search for chemical resistant gloves using the chemical CAS number or chemical name. There will be information relating to the barrier performance of the gloves. The information may be comprised of experimental data or estimations, based on extrapolations from experimental data. The user can also search for gloves using the product name or material. The database also has ratings for permeation breakthrough times and a degradation test.
Official Database

Ansell Chemical Resistance Guide -- Permeation & Degradation Data, 8th Edition: This guide provides permeation/degradation ratings for different Ansell gloves.
Official Guide

(Canada) Superior Glove Works Ltd.

Work Gloves 101: This guide provides general glove selection information for various industries.
Official Guide

Duke University, Trinity College of Arts & Sciences

The Right Glove for the Right Job (Focused on laboratory staff): This guide contains information on glove degradation and permeation for various types of chemicals.
Official Guide

(EU) Shield Scientific

Glove Specifications: This company provides specifications for their glove products. Each product is tailors to specific use; hence each specification sheet will provide information such as (1) product catalogue number, applicable norms, and material; (2) physical properties of product material; and (3) additional data such as biocompatibility, micro-organism/virus resistant, and level of chemical resistance.

Manufacturer's Specifications

Understanding glove standards: This guide is an overview of the European Standard for protective disposable gloves. Disposable gloves in this category are typically those gloves that provide protection against chemical splashes and microorganisms. For these gloves, the following normative references may apply: EN 374-1:2003 (terminology and performance requirements), EN 374-2:2003 (resistance to penetration by chemicals and microorganisms), EN 16523-1:2015 (supersedes EN 374-3:2003 – resistance to permeation by chemicals), EN 388:2003 (mechanical risks), and EN 420:2003 + A1:2009 (general requirements for gloves).
Official Guide

Glove Chemical Resistance Guide: This guide is developed by Shield Scientific to help users in their risk assessments for evaluating personal protection to chemical exposure. Data can be selected either by CAS number, chemical name, or product type. The testing has been conducted by reputable testing laboratories (Respirex, Proqares & Centexbel), according to EN 16523-1:2015 (Determination of material resistance to permeation by chemicals – Part 1: permeation by liquid chemical under conditions of continuous contact). This standard supersedes EN 374-3:2003. Data provided was based on gloves tested under laboratory conditions.
Official Guide

Glove Selection Guide by Risk/Use: This guide is developed by Shield Scientific to help users chose the right glove based on intended usage.
Official Guide

(EU) Guide Gloves

Chemical Protection Guide: This chart gives a recommendation about which materials and which gloves provide the best protection against various types of chemicals. The table is prepared using EN374-3:2003 permeation breakthrough times.
Official Guide

List of EN standards: This page lists EN standards for PPE including requirements, test performance level, and other ratings which are specific to each type of gloves.
Official Guide

Industry Programs on Worker Safety

There are many voluntary standards developed by industry trade associations. We note a few below.

1. **American Chemistry Council Responsible Care® Program**
   See https://responsiblecare.americanchemistry.com/Responsible-Care-Program-Elements/Product-Safety-Code/Responsible-Care-Product-Safety-Code-PDF.pdf

2. **National Association of Chemical Distributors (NACD) Responsible Distribution Program**
See https://www.nacd.com/default/assets/File/176thcycle_cmp.pdf

3. **Society of Chemical Manufacturers and Affiliates ChemSteward Program**
See http://www.socma.com/chemstewards

4. **American Petroleum Institute Process Safety Assessments Program**
See https://www.api.org/products-and-services/site-safety

Attachment D

Body of Knowledge

SDS and Label Authoring Registry

AIHA®
Protecting Worker Health

About AIHA®

Founded in 1939, the American Industrial Hygiene Association® (AIHA®) is one of the largest international associations serving the needs of industrial/occupational hygiene professionals practicing in industry, government, labor, academic institutions, and independent organizations.

For more information, visit www.AIHA.org

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Background

AIHA® and its selected members worked collaboratively to develop the technical framework, known as the Body of Knowledge (BoK), that outlines the knowledge and skills a competent person should possess and be able to demonstrate when authoring safety data sheets (SDS) and labels. In September 2015, a panel of subject matter experts was appointed to revise the SDS & Label Authoring BoK and develop a subsequent Job/Task Analysis (JTA) survey to collect input, perspective, and feedback from relevant stakeholders to identify the essential knowledge and skills required for competent SDS and label authoring. The subject matter expert project team included a subset of SDS and label authoring Registrants.

In December 2015, the JTA survey was made available to AIHA® SDS and Label Authoring Registrants. The survey results were used to finalize the content for the SDS and Label Authoring BoK.

The BoK document was approved by the subject matter expert project team June 2016.

SDS & Label Authoring

Occupational Definition

This document provides an organized summary of the collective knowledge and skills necessary for competent SDS and label authoring. This Body of Knowledge (BoK) will be used by AIHA to establish a framework to assist the prospective registrant in preparing for the exam. Prior to sitting for the SDS and Label Authoring Registry's Competency Assessment, the applicant should ensure that they are proficient in these knowledge areas.

This BoK is not intended to define or stipulate employer hiring criteria. It is the employer's responsibility to ensure that each employee understands his or her specific job and has met the minimum criteria established by relevant regulations, standards, and the specific industry, facility, or project.

Skills

Performance-based training incorporates performance tasks (performance assessments) that build on content knowledge. These demonstrations of knowledge and skills document competence.

Knowledge Test

The knowledge test consists of 75 multiple choice questions that evaluate your knowledge in areas in which a SDS and label authoring specialist should be proficient. These questions involve basic concepts in toxicology, ecotoxicology, industrial hygiene, chemistry, and emergency response for chemicals. You will be expected to perform mathematical calculations and conversions related to hazard classification and SDS. A formula sheet will be provided. It will contain all the formulas that you will need and all the Globally Harmonized System of Classification and Labeling of Chemicals international standard (GHS) classification tables or decision logic charts needed for substance and mixture classification questions. This BoK provides a blueprint of the type of questions you can expect in each knowledge area.

Knowledge Areas

Table 1 describes the knowledge and skills that constitute competent SDS and label authoring.

1.0 Math and Science (19%)

1.A. General mathematics & computation

1.A.1. Calculate composition percentages

1.A.2. Calculate percentages of pure substances in mixtures of mixtures

1.A.3. Convert and calculate ppm, ppb, and ppt into weight/volume percent

1.A.4. Convert ppm to mg/L, mg/mL, and g/L; and vice versa for liquids and solids

1.A.5. Convert ppm to mg/L or mg/m3 and vice versa for gases, vapors, dust and mists

1.A.6. Understand the relationship between density and specific gravity

1.A.7. Convert temperature in Celsius to Fahrenheit and vice versa

1.A.8. Understand standard unit/metric system

1.B. General Chemistry

1.B.1. Understand the differences between atoms elements and compounds

1.B.2. Demonstrate an understanding of the major types of chemical identifiers and their use (ex: CAS numbers, UN Numbers, EINECS, etc.)

1.B.3. Demonstrate an understanding of the main types of compounds (organic, inorganic, monomers, polymers, surfactants, solvents, acid, bases)

1.B.4. Identify key characteristics of the main types of organic compounds (Alkanes, Alkenes, Alkynes, Aromatic Hydrocarbons, Alcohols, Amines, Acids, Amides, Esters, Ethers, Halogens, Nitros, Aldehydes, Ketones, Isocyanates, Peroxides)

1.B.5. Understand the main chemical and physical properties included on a SDS under the GHS

1.B.6. Demonstrate an understanding of the various types of solubility (highly soluble, soluble, slightly soluble, nonsoluble)

1.B.7. Understand what pH is and how it is calculated

1.B.8. Understand and identify reaction products

1.B.9. Understand the differences between stability and reactivity

1.B.10. Differentiate between the three physical forms (gas, liquid, solid) and understand the hazard potentials for each

1.B.11. Understand the route of exposure potential for the different physical forms

1.B.12. Understand the meaning of physical property with regard to the hazard of the property

1.B.13. Understand the meaning of physical properties and their test methods to determine the end point (e.g. vapor pressure, boiling point, flash point)

1.B.14. Understand the behaviors of mixtures vs substances

1.B.15. Understand how temperature and pressure impact other hazards outside the scope of the specifically defined hazard classes

2.0 Hazard Communication (20%)

2.A. GHS Concepts

2.A.1. Understand the scope of the GHS

2.A.2. Understand the structure of the purple book

2.A.3. Demonstrate an understanding of the scope, application and limitations of the GHS

2.A.4. Apply knowledge of GHS concepts including the building block approach and application

2.A.5. Understand GHS definitions like hazard class, hazard category, weight of evidence, etc.

2.A.6. Demonstrate an understanding of which elements of the GHS are applicable to the different sectors (transport, workplace, consumer products)

2.A.7. Apply knowledge of GHS Classification Principles for substances and mixtures

2.A.8. Demonstrate an understanding of using cut-off values

2.A.9. Understand labeling concepts

2.A.10. Demonstrate an understanding of the general guidelines for SDS reader comprehension

2.A.11. Demonstrate an understanding of the relationship between each section and piece of data on the SDS document so that consistency can be achieved throughout the document

2.A.12. Identify data sources on the SDS (mixture testing versus component data)

2.A.13. Understand the term article

2.A.14. Demonstrate an understanding of the building block approach

2.A.15. Understand and identify the harmonized GHS label elements

2.B. SDS Content & Label

2.B.1. Demonstrate an understanding of identifying chemicals (IUPAC, common names, CAS, EC)

2.B.2. Understand the concepts found on a safety data sheet and the audience(s) for each section

- Identification (Product Name/Manufacturer Information including Emergency Contact Information/Recommended Use/Restricted Use)
- Hazard Identification
- Composition
- First-aid measures
- Fire-fighting measures
- Accidental release measures
- Handling and storage
- Exposure Controls and Personal Protective Equipment
- Physical and chemical properties
- Stability and reactivity
- Toxicological information
- Ecological information
- Disposal considerations
- Transport information
- Regulatory Information
- GHS labeling requirements
- NFPA or HMIS ratings (Alternative labeling systems)
- Other information

2.B.3. Know the process in which an SDS is developed (Order of section development)

2.B.4. Know how to review an SDS for internal consistency

2.B.5. Understand the sections, required format, and the content of a GHS Safety data sheet

2.B.6. Demonstrate knowledge for the selection of label elements (pictogram(s), signal word, hazard statement(s) and precautionary statement(s) based on a GHS Classification

2.B.7. Know the elements of a GHS compliant label

2.B.8. Understand how a GHS label is developed using the tables in Annex 3 of the GHS

2.B.9. Know the order of precedence for the label elements in the GHS

3.0 Physical Hazards (9%)

3.1. Apply knowledge of the 17 physical hazard classes and when to use them

3.2. Understand the use of ISO 10156:2010 in calculating the flammability of gas mixtures under GHS

3.3. Understand how the hazard classes under the GHS physical hazards section relate to and can be used to determine the transportation information - hazard class, packing group, etc. (**Note: Formal training on transportation regulations is required before an SDS author can apply this to section 14 of an SDS.)

3.4. Familiarize yourself with the test methods used to determine physical hazards and how to interpret test data for the various classes

3.5. Demonstrate an understanding of Hazards Not Otherwise Classified (HNOC) and where they are implemented

3.6. Demonstrate an understanding of combustible dust

4.0 Health Hazards (21%)

4.A. General Concepts

4.A.1. Understand data conversion (1 hour to 4 hour for inhalation toxicity data, ppm to mg/L for vapor toxicity)

4.A.2. Distinguish between the different forms of matter (gas, vapor, mist, dust)

4.A.3. Understand the relevant ingredients concept for untested mixture classification in the hazard classes that use additivity (Acute Toxicity, Skin Corrosion/Irritation, Serious Eye Damage/Eye Irritation, Target Organ Toxicity – Single Exposure Category 3, Aspiration Hazard, and Hazardous to the Aquatic Environment)

4.A.4. Convert range data or acute toxicity category to a point estimate for mixture calculations

4.A.5. Understand how to properly handle ingredients with unknown acute toxicity

4.A.6. Apply knowledge of the 10 health hazard classifications and when to use them for substances

4.A.7. Understand the GHS tiered approach to classifying mixtures (e.g. tested mixtures, bridging principles, untested mixture calculations)

4.A.8. Demonstrate an understanding of HNOCs and where they are implemented

4.B. General Toxicology Concepts

4.B.1. Understand the term toxicology

4.B.2. Understand how chemicals move into and out of the body: absorption, distribution, metabolism and excretion

4.B.3. Understand dose-response relationship

4.B.4. Understand the threshold response concepts (NOEL, NOAEL, LOAEL)

4.B.5. Understand the adverse health effect concept

4.B.6. Distinguish between immediate (acute) vs. Delayed (chronic) effects

4.B.7. Distinguish between Local vs. Systemic effects

4.B.8. Distinguish between Reversible vs. Irreversible effects

4.B.9. Understand toxicity tests

4.B.10. Understand preferred species for acute toxicity tests

4.B.11. Understand when Additivity is used and when it is not (skin corrosion/irritation, serious eye damage/eye irritation)

4.B.12. Understand weight of evidence

4.C. General Biology

4.C.1. Demonstrate an understanding of the structure and function of target organs (e.g. respiratory system, kidney, liver, nervous system)

5.0 Environmental Hazards (8%)

5.A General Ecotoxicology Concepts

5.A.1. Understand the toxicity endpoints: LD50, LC50, EC50, NOEC

5.A.2. Understand and identify the different methods and durations for acute aquatic toxicity testing and the organisms used

5.A.3. Understand and identify the different methods of classification for chronic aquatic toxicity testing and the organisms used

5.A.4. Demonstrate an understanding of persistence testing (i.e., biodegradation, hydrolysis, photolysis)

5.A.5. Demonstrate an understanding of bioconcentration and bioaccumulation (logKow/Pow)

5.A.6. Demonstrate an understanding of degradation

5.A.7. Understand the concept of M factor

5.A.8. Understand how to apply the criteria for Ozone Depleting Potential under the GHS

5.A.9. Apply criteria for classifying substances for acute and chronic aquatic toxicity potential including the concept of different trophic levels (fish, aquatic inverts, aquatic plants)

5.A.10. Understand the GHS tiered approach to classifying mixtures (e.g. tested mixtures, bridging principles, untested mixture calculations) (i.e. Summation and Additivity)

5.A.11. Understand how to properly handle ingredients with unknown hazards to the aquatic environment

6.0 Industrial Hygiene & Safety (12%)

6.1. Determine which exposure limit to include in the SDS based on the exposure limits given

6.2. Understand the types of threshold limit values (i.e., TWA, STEL, Ceiling Limit, IFV, Excursions, BEI, Respirable Fibers, Dust Limits – total, inhalable, thoracic fraction and respirable)

6.3. Understand significant routes of exposure for various physical states

6.4. Understand the applicability of engineering controls (i.e., ventilation)

6.5. Demonstrate an understanding of the PPE recommendations related to hazards, quantity, and conditions of use

6.6. Understand and apply appropriate first-aid measures based on classification

6.7. Demonstrate an understanding of special treatments for exposure

6.8. Consider special needs that a physician should be made aware of when completing the first-aid section (section 4) of the SDS

6.9. Differentiate between suitable/unsuitable controls for fire types

6.10. Understand and identify the specific hazards arising from burning chemical fires

6.11. Demonstrate an understanding of compatible and incompatible chemical placement

6.12. Select precautionary statements for safe handling based on classification and physical properties

6.13. Recommend personal precautions, protective equipment and protective measures for spilled product(s)

6.14. Understand how stability and reactivity relate to an SDS

6.15. Identify the drivers behind chemical incompatibility

6.16. Apply knowledge of chemical incompatibility

7.0 Risk Analysis (2%)

7.1. Understand the relationship between risk, hazard, and exposure

7.2. Understand how consumer product labeling can be based on the likelihood of injury (see GHS Annex 5)

7.3. Understand how the term "biologically available" can be considered when performing hazard classification

8.0 International GHS Implementation, Associated Regulations & Consensus Standards (8%)

8.1. Understand the US OSHA specific hazard classes

8.2. Demonstrate an understanding of environmental regulations that would impact Section 15 of the SDS sheet (i.e., CERCLA, SARA, TSCA, etc.)

8.3. Understand SDS content required by EPCRA (SARA 313)

8.4. Demonstrate an understanding of dangerous goods transportation

8.5. Identify and list OEL/BEI for different areas/countries (i.e. PEL, TLV, MAK, REL)

8.6. Demonstrate understanding of Right to Know Laws

8.7. Apply general understanding of disposal regulations

8.8. Demonstrate an understanding of Inventory and chemical control laws (US TSCA, Canadian DSL, NDSL, etc.)

8.9. Demonstrate basic knowledge of EU CLP Annex VI

8.10. Understand the characteristics of a study that adds to its weight of evidence for classification (e.g., Good Laboratory Practice (GLP), statistical significance, etc.)

8.11. Know requirements for OSHA's Hazard Communication Standard 2012

8.12. Understand which ingredients or impurities must be disclosed in an OSHA HCS 2012 SDS

8.13. Understand what information may be claimed as trade secret under OSHA HCS 2012

8.14. Be familiar with the comprehensibility concepts for SDSs and labels (e.g., ANSI Z1291/Z4001)

SDS and Label Authoring Registry

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DISCLAIMER

This Study Guide provides information regarding (1) identified knowledge areas, to supplement what is outlined in the Body of Knowledge for the SDS and Label Authoring Registry Program, and (2) the format of the current examination. This Study Guide is not intended to teach the competencies measured by the examination, but rather to give you an understanding of test content, structure and procedure so that you may approach the examination with the confidence that comes with knowing what to expect.

The authors make no claims to know what will be on the exam or that this study guide contains all critical information. The material herein is not intended to be a comprehensive handling of the subject matter. It is intended to provide one means for you to self-assess your knowledge and competencies, and to provide guidance into those areas where review may be necessary.

This is a joint publication of American Industrial Hygiene Association, the Society for Chemical Hazard Communication, and AIHA Registry Programs, LLC (known as "the PUBLISHERS").

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If you are looking for additional information about policies and process related to taking the SDS and Label Authoring Registry exam, please visit www.aiharegistries.org

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The purpose of this study guide is to assist the prospective registrant in preparing for the exam. This proficiency is currently based on Revision 5 of the GHS.

The proficiency assessment takes four hours to complete. You are allowed 2 hours for the knowledge and 2 hours for the practical skills assessment. They are scored separately. You must pass both to become registered. If you do not pass one part but pass the other, you will only need to re-take the part you did not pass again.

The Knowledge Test

The knowledge test consists of 75 multiple choice questions that evaluate your knowledge in areas in which a SDS and label authoring specialist should be proficient. These questions involve basic concepts in toxicology, ecotoxicology, industrial hygiene, chemistry, and emergency response for chemicals. You will be expected to perform mathematical calculations and conversions related to hazard classification and SDS. A formula sheet will be provided. It will contain all the formulas that you will need and all the Globally Harmonized System of Classification and Labeling of Chemicals international standard (GHS) classification tables or decision logic charts needed for substance and mixture classification questions. To do well on this part of the exam, you need a solid knowledge in the rubrics below. This guide provides an overview of the type of questions you can expect in each rubric area.

1. Math and Science
2. Hazard Communications
3. Physical Hazards
4. Health Hazards
5. Environmental Hazards
6. Industrial Hygiene and Safety
7. Risk Analysis
8. International GHS Implementation, Associated Regulations and Consensus standards

Rubric 1 – Math and Science

There are two types of questions that involve this rubric. The first kind are those specifically designed to test your understanding of important math and chemistry concepts related to hazard communication. The second kind are those that are testing another proficiency, but require knowledge of math and chemistry to answer them correctly. You should be able to:

- Calculate composition percentages
- Calculate percentages of pure substances in mixtures of mixtures
- Understand calculating molar solutions
- Understand parts per million (ppm), parts per billion (ppb), and parts per trillion (ppt)
- Be able to convert and calculate ppm, ppb, and ppt
- Convert ppm to mg/L, mg/mL, and g/L; and vice versa for liquids and solids
- Convert ppm to mg/L or mg/m3 and vice versa for gases and vapors
- Understand the relationship between density and specific gravity
- Calculate density or specific gravity
- Convert Temperature in Celsius to Fahrenheit and vice versa
- Understand standard units/metric system
- Understand the differences between atoms and molecules, and elements and compounds

- Know the subatomic particles (electrons, protons, and neutrons)
- Know the major types of chemical identifiers and their use (ex. CAS numbers, UN Numbers, EINECS, etc.)
- Know the main types of compounds (organic, inorganic, monomers, polymers, surfactants, solvents)
- Know key characteristics of the main types of organic compounds (Alkanes, Alkenes, Alkynes, Aromatic Hydrocarbons, Alcohols, Amines, Acids, Amides, Esters, Ethers, Halogens, Nitros, Aldehydes, Ketones, Isocyanates, Peroxides)
- Know the differences between acids and bases
- Understand oxidizing reactions and what makes a chemical an oxidizer
- Understand reducing reactions and what makes a chemical a reducing agent
- Know the definitions of the three physical forms (gas, liquid, solid)
- Understand the route of exposure potential for the different physical forms
- Know the main physical properties included on a SDS under the GHS
- Understand the meaning of physical properties and their test methods to determine the end point (e.g. vapor pressure, boiling point, flash point)
- Know the various types of solubility (highly soluble, soluble, slightly soluble, nonsoluble)
- Understand what pH is and how it is calculated
- Understand the difference between mixtures and compounds
- How to identify data sources on the SDS (mixture testing versus component data)
- Understand and identify reaction products
- Understand the differences between stability and reactivity and how they relate to a SDS

Examples of a more general concept question might be:

Q: What is the definition of a polymer?

A: A large molecule made up of chains or rings of linked monomer units.

Q: A millimeter of mercury (mmHg) is a unit of measure for which of the following?

A: Vapor Pressure

An example of a calculation question might be:

Q: A substance is 10% of a raw material, and the raw material is 20% of a product. What percent of the product is the substance? Assume both the raw material and the product are simple mixtures.

A: 2%

Q: Convert 45°C to degrees F (formula will be provided)

A: 113°F

Rubric 2 – Hazard Communication

The questions in this topic area are intended to test your knowledge of the general concepts of hazard communication found in the GHS purple book. Specifically you should be knowledgeable of Part 1 of the GHS. You should be able to answer questions on:

- The history of the GHS
- The structure of the purple book
- The scope, application and limitations of the GHS
- Concepts in the GHS including the building block approach and application
- GHS definitions like hazard class, hazard category, weight of evidence, etc.
- Which elements of the GHS are applicable to the different sectors (transport, workplace, consumer products)
- GHS Classification Principles for substances and mixtures
- The use of cut-off values
- Bridging principles
- Labeling concepts (use of label tables, elements of a compliant label)
- Understand the general guidelines for SDS reader comprehension
- SDS content – know the various Sections of the SDS and what information appears in each Section
- Understand how different sections of the SDS interrelate to form a cohesive whole
- Understand the term article
- Understand and identify the harmonized GHS label elements
- Identify alternative labeling systems (NFPA, HMIS, etc.)

Examples of questions in this section might be:

Q: What is the correct pictogram for a pyrophoric solid?

A: Flame

Q: Which of the bridging principles refers to the situation where a mixture is assumed to be substantially equivalent to a previously manufactured lot of the same mixture?

A: Batching

Q: What Section of the SDS includes the product labeling?

A: Section 2

Rubric 3 – Physical Hazards

You must be familiar with the GHS criteria for classification for all 16 physical hazard classes. You will be given physical data for a substance or mixture and be expected to identify which hazard class would apply and assign the hazard class and category correctly. Some questions may be more general and concept based. Others will require specific classifications. When a specific classification is required, the applicable GHS classification table or flow-diagram will be provided on the formula sheet. You should be able to answer questions on:

- Identify the 17 GHS Physical Hazard classes and when to use them
- Understand the test methods and interpret the test data for various classes
- Understand the concept of "Hazards Not Otherwise Classified" and how it applies to physical hazards
- Understand the concept of combustible dust

An example of a more general concept question might be:

Q: What data elements are needed to classify flammable liquids?

A: Flash Point and Boiling Point

An example of a specific classification question might be:

Q: Provide the hazard class/category for a liquid with a boiling point of 45°C and flash point of 12°C. (In this case the classification table for flammable liquids will be provided)

A: Flammable Liquid Category 2

Rubric 4 – Health Hazards

You must be familiar with both general toxicology concepts and the GHS criteria for classification for all 10 health hazard classes. You will be given health hazard data for a substance or mixture and be expected to identify which hazard class would apply and assign the hazard class and category correctly. Some questions may be more general and concept based. Others will require specific classifications. When a specific classification is required, the applicable GHS classification table or flow-diagram will be provided on the formula sheet.

- The general toxicology concepts you should be prepared to answer questions on include:
- The definition of toxicology and the types of toxicology
- How chemicals move into and out of the body: absorption, distribution, metabolism and excretion
- Dose-response relationship
- Threshold response concepts (NOEL, NOAEL, LOAEL)
- Adverse health effect concept
- Immediate (acute) vs. Delayed (chronic) effects
- Local vs. Systemic effects
- Reversible vs. Irreversible effects
- Toxicity tests, preferred species for classification

- Weight of evidence
- Understand when additivity is used and when it is not
- Understand the GHS tiered approach to classifying mixtures (tested mixtures, bridging principles, untested mixture calculations, cut-off values)
- Understand the concept of "Hazards Not Otherwise Classified" and how it applies to health hazards

Some important GHS health hazard concepts

- Data conversion (1 hour to 4 hour for inhalation toxicity data, ppm to mg/L for vapor toxicity)
- Forms of matter (gas, vapor, mist, dust)
- Relevant ingredients for mixture classification
- Converting range data or acute toxicity category to a point estimate for mixture calculations
- Bridging principles
- How to handle ingredients with unknown acute toxicity

You should also be prepared to evaluate specific toxicity data provided and determine the correct GHS classification based on that data. The following are some examples of the kind of questions you might see. You will be provided all applicable classification criteria tables or flowcharts and any needed formulas.

Q: The oral LD50 of substance A in rats is 400 mg/kg. What is the classification?

A: Acute Toxicity Oral Category 4

Q: The inhalation LC50 in rats for a substance as a vapor is 0.8 mg/L/1 hour. What is the classification? (Remember to convert to a 4 hour ATE)

A: Acute Toxicity Inhalation Category 1

Q: A mixture consists of 2 substances, A and B, each present at 50%. The oral LD50 of substance A is 100 mg/kg in rats, the oral LD50 of substance B is 500 mg/kg in rats. What is the classification of the mixture? (FYI: If you are given the inhalation toxicity for vapors in ppm – remember to convert to mg/L to classify).

A: Calculated ATE Oral = 167 mg/kg; Acute Toxicity Oral Category 3

Q: A substance causes irreversible skin damage in a contact time of 2 minutes in a rabbit study. What is the classification of the substance?

A: Skin Corrosion Category 1A

Q: A mixture contains an ingredient A at 0.05% that is classified as a skin sensitizer category 1A and 0.06% of an ingredient B that is classified as a skin sensitizer category 1A. Is the mixture classified as a skin sensitizer?

A: No (unless they are chemically similar like isocyanates)

Rubric 5 – Environmental Hazards

You must be familiar with both general ecotoxicology concepts and the GHS criteria for classification for environmental hazard classes. You will be given environmental hazard data for a substance or mixture and be expected to identify which hazard class would apply and assign the hazard class and category correctly. Some questions may be more general and concept based. Others will require specific classifications. When a specific classification is required, the applicable GHS classification table or flow-diagram will be provided on the formula sheet.

The general ecotoxicology concepts you should be prepared to answer questions on include:

- Toxicity endpoints: LC50, EC50, NOEC
- Acute aquatic toxicity testing for classification – methods, duration and organisms used
- Chronic aquatic toxicity testing for classification – methods and organisms used
- Abiotic Hazards – Global Warming Potential, Ozone Depletion, Acidification
- Physical and Chemical Properties important in understanding environmental fate
- Bioconcentration and bioaccumulation (logKow/Pow)
- Persistence Testing – Biodegradation, Hydrolysis, Photolysis
- Understand the concept of the M-factor
- Understand the GHS tiered approach to classifying mixtures (tested mixtures, bridging principles, untested mixture calculations – Summation, Additivity)
- How to handle ingredients with unknown hazards to the aquatic environment

Additional concepts included in this section are:

- Environmental considerations for accidental releases
- Disposal considerations

You should also be prepared to evaluate specific ecotoxicity, bioaccumulation and/or biodegradation data provided and determine the correct GHS classification based on that data. Knowledge of both substance and mixture classification will be tested. The following are some examples of the kind of questions you might see. You will be provided all applicable classification criteria tables or flowcharts and any needed formulas.

Q: What is the endpoint used to derive the LC50 in fish?

A: Death of half of the fish

Q: A product contains 3 chemicals. Chemical A has an Acute toxicity to fathead minnows of 1.5 mg/L/96hr and is 45% of the product. Chemical B has an Acute toxicity to fathead minnows of 110 mg/L/96hr and is 35% of the product. Chemical C has an Acute toxicity to fathead minnows of 0.2 mg/L/96hr and is 20% of the product. What is the calculated additive toxicity of the product?

A: Calculate ATE = 0.77 mg/L

Q: What is the multiplying factor for a substance with an EC50 in daphnia of 0.004 mg/L/48hr?

A: M = 100

Q: Is a chemical that exhibits a biodegradation rate of 83% in an OECD301 test readily biodegradable?

A: Yes

Q: Using the summation method, determine the ecotoxicity classification for the following mixture. Component A is present at 1%, is classified as acute 1 and has an M factor of 10. Component B is present at 15%, is classified as acute 1, and has an M factor of 1. Component C is present at 34% and is classified as acute 2. And component D is present at 50% and is classified as acute 3.

A: Aquatic Toxicity Acute Category 1

Rubric 6 – Industrial Hygiene and Safety

The questions in this topic area are intended to test your knowledge of the general concepts of industrial hygiene and safety as they relate to authoring SDS and labels. Topic areas for questions include:

- First aid and notes-to-physicians
  - How first aid statements on the label are selected
  - The purpose of first aid
  - First aid basics
- Firefighting and control
  - The fire tetrahedron, classification of fires and how the various extinguishing media work to extinguish the fire
  - Identifying unsuitable extinguishing media
  - Identifying hazardous combustion products
- Accidental release measures
  - Using hazards and properties to recommend procedures and clean up
- Storage and handling recommendations
  - Storage compatibility
- Stability and Reactivity Considerations related to storage and use
- Exposure limits
  - Types of limits (TWA, STEL, Ceiling Limit, IFV, Respirable Fibers, Dust Limits – total, inhalable, thoracic fraction and respirable)
  - Notations – SEN, SKIN
  - DN(M)EL, PNECs (these are limits derived from an EU REACH process and appear on SDS in some cases)
  - BEI
- Hierarchy of Control Methods
  - Elimination→Engineering Controls→Administrative Controls/Work Practices→PPE
- Engineering controls
  - Types of ventilation (general vs local exhaust)
  - Process controls
- Personal protective equipment
  - Respiratory Protection – types, selection parameters, types of filters and cartridges
  - Skin Protection – types, permeation, breakthrough time, degradation, penetration

- Eye/Face Protection – use of types (safety glasses, goggles, faceshield, other)

Examples of questions in this section might be:

Q: What is the most appropriate place to sample when evaluating a worker exposure?

A: The worker's breathing zone

Q: What is the definition of a TWA exposure limit?

A: A time weighted average meaning average exposure over an 8-hour shift

Q: Convert a time-weighted average (TWA) concentration of 700 milligrams per cubic meter (mg/m3) to an equivalent concentration in parts-per-million (ppm). The molecular weight of the substance is 125 Daltons.

A: 137.2 ppm (137 ppm)

Q: What does the notation SEN mean when associated with an occupational exposure limit?

A: The chemical is a sensitizer

Q: Which type of engineering control is most appropriate for a volatile chemical classified as a carcinogen?

A: Enclosure

Q: For which of the following types of fires is water the most effective extinguishing agent?

A: Class A (ordinary combustibles)

Q: Would a glove with a breakthrough time of 3 minutes and permeation rate of 100 ug/cm2/min for a substance be appropriate to recommend for protection against that substance?

A: No

Rubric 7 – Risk Analysis

This is a minor rubric for the exam. Only a few questions on the test will come from this topic area. The questions in this topic area are intended to test your knowledge of the general concepts of risk analysis as they relate to authoring SDS and labels. Topic areas for questions include:

- Definition of Risk, Risk Analysis and Risk Assessment
- Relationship between risk and hazard and exposure
  - Risk = hazard x exposure
- Definition of Hazard (Toxicity)
- Definition of Exposure
- Steps in the Risk Assessment
  - Hazard Identification

  - Dose-Response Assessment
  - Exposure Assessment
  - Risk Characterization
- Use of Risk Assessment in the GHS
  - Limited to chronic health hazards in consumer product setting
- Risk characterization for carcinogens vs non-carcinogens
- Definite the term "biologically available" and how it relates to Hazard Classification

Examples of questions in this topic area include:

Q: What hazards can risk based labeling be applied to?

A: Chronic Health hazards for consumer products

Q: What are the steps in the risk assessment process?

A: Hazard Identification -> Dose-Response Assessment -> Exposure Assessment -> Risk Characterization

Q: As a default, the unit risk for the cancer endpoint is calculated from which of the following?

A: Slope Factor (CSP) / Potency Factor (CFP)

Q: What is the correct formula for risk?

A: Risk = Hazard x Exposure or Risk = Toxicity x Exposure

Rubric 8 - International GHS Implementation, Associated Regulations and Consensus Standards

This is also a minor rubric for the exam. Only a few questions on the test will come from this topic area. The questions in this topic area are intended to test your knowledge of the general concepts GHS implementation around the world and general concepts about other chemical regulation, mainly chemical control laws.

- Understand the US-specific OSHA Hazard Classes
- Demonstrate an understanding of environmental regulations that would impact Section 15 of the GHS SDS (CERCLA, SARA, TSCA, etc)
- Demonstrate and understanding of inventory and chemical control laws (REACH, DSL, PICCS, TSCA, etc.)
- Demonstrate a basic knowledge of EU CLP Annex VI (harmonized classifications in Europe)
- Know the requirements of international GHS implementation (EU CLP, Canadian WHMIS, US HazCom 2012, etc.)
- Understand which ingredients and impurities must be disclosed on a SDS in various regions
- Understand trade secret protections in various regions

Examples of questions in this topic area include:

Q: What government body is responsible for implementation of the GHS in the EU?

A: ECHA

Q: What hazard class is unique to the New Zealand implementation of the GHS?

A: Terrestrial Ecotoxicity

Q: What are the US OSHA specific hazard classes?

A: Combustible dust, Pyrophoric gases, Simple asphyxiants

Q: What is the purpose of a national chemical inventory?

A: To assure risk assessment of new chemicals introduced into commerce in a country

Knowledge Test Practice Exam

1. Which of the following statements about atoms is true?

    a. A positively or negatively charged atom is known as an isotope.

    b. The number of protons determines the chemical element.

    c. The number of protons determines the isotope of the element.

    d. The ratio of protons to neutrons determines the charge of an atom.

2. A substance is 5% of raw material A, 20% of raw material B, and not present in raw material C. The ratio of the raw materials is 20:20:60 (A:B:C). What percentage of the product is the substance? Assume both the raw materials and the product are simple mixtures.

    a. 3%

    b. 5%

    c. 7%

    d. 9%

3. Convert -58 degrees Fahrenheit (°F) into degrees Celsius (°C).

    a. -32

    b. -162

    c. -50

    d. -68

4. Which of the following is known as the ratio of the mass of a gas or vapor to the mass of an equal volume of air?

    a. Vapor pressure

    b. Vapor density

    c. Bulk density

    d. Saturated vapor concentration

5. Which of the following defines a vapor?

    a. The gaseous form of a substance or mixture released from its liquid or solid state.

    b. An airborne dispersion of solid particles formed by the condensation of volatilized material.

    c. A visible liquid aerosol formed by condensation.

    d. A dispersion of microscopic solid particles and/or liquid particles in a gaseous medium.

6. Which of the following are the three primary types of hazards?

    a. Physical, toxic, and environmental

    b. Physical-chemical, health, and environmental

    c. Explosive, corrosive, and acute aquatic toxicity

    d. Physical, health, and environmental

7. Which of the following are the acceptable signal words?

    a. Danger, warning, and caution

    b. Poison, danger, and warning

    c. Danger and warning

    d. Poison and warning

8. A Safety Data Sheet (SDS) is composed of how many headings (sections)?

    a. 16

    b. 17

    c. 8

    d. 12

9. Which of the following defines a weight of evidence assessment?

    a. All available relevant information are considered together.

    b. Only animal studies, in vitro studies, and clinical studies are considered.

    c. Only the most relevant study is used.

    d. Only the most recent studies are used.

10. For which of the following target audience is comprehensibility of particular importance?

    a. Workplace

    b. Consumers

    c. Emergency responders

    d. Transport

11. Which of the following definitions best describes an oxidizing gas?

    a. Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air.

    b. Any gas which is flammable due to release of the oxygen in its structure upon heating.

    c. Any gas which participates in a redox reaction, but does not impact the hazard of surrounding materials.

    d. Any gas that is oxidized and made more flammable by the presence of another material which provides an oxygen-rich environment.

12. Which of the following substances contains a chemical group that is indicative of a self-reactive substance?

    a. Phenol

    b. Xylene

    c. Ethanol

    d. Methanesulphonyl chloride

13. Which of the following data are generally not used in an evaluation strategy for skin corrosion/ irritation?

    a. Data from structure activity relationship (SAR) analysis

    b. Data from historical human experience

    c. pH data

    d. Data from an eye irritation/corrosion test

14. What is the classification of an untested mixture that contains 5% of a substance classified as a Germ Cell Mutagen category 2?

    a. Germ Cell Mutagen Category 1A

    b. Germ Cell Mutagen Category 1B

    c. Germ Cell Mutagen Category 2

    d. Not classified as a germ cell mutagen.

15. Calculate the acute toxicity estimate (ATE) for the following mixture. 40% of a substance with an oral lethal dose 50% [LD(50)] of 500 mg/kg, 20% of a substance with an oral LD(50) of >2000 mg/kg with no observed clinical signs of toxicity, 20% of a substance with an oral LD(50) of 3500 mg/kg, and 20% of a substance with an unknown oral LD(50).

    a. 1045 mg/kg

    b. 836 mg/kg

    c. 1167 mg/kg

    d. 933 mg/kg

16. What is the classification of a substance that is known to cause transient central nervous system effects in humans that can lead to impaired judgment?

    a. Specific Target Organ Toxicity - Single Exposure Category 3

    b. Specific Target Organ Toxicity - Repeat Exposure Category 2

    c. Specific Target Organ Toxicity - Single Exposure Category 2

    d. Specific Target Organ Toxicity - Single Exposure Category 1

17. Which of the following is the preferred test species for the evaluation of acute toxicity by the inhalation route?

    a. Mouse

    b. Rat

    c. Rabbit

    d. Guinea Pig

18. Which of the following statements is the most appropriate definition of the ecotoxicological end-point No Observed Effect Concentration (NOEC)?

    a. Any test concentration that exhibits no statistically significant adverse effects.

    b. The test concentration immediately above the lowest tested concentration with statistically significant adverse effects.

    c. The test concentration immediately below the lowest tested concentration with statistically significant adverse effects.

    d. The lowest test concentration that exhibits an effect relative to the control.

19. How should the following aquatic toxicity data be used to determine the acute aquatic hazard classification of a substance: 96-hr fish LC(50) = 12 mg/l; 48-hr crustacea EC(50) = 1.3 mg/l; 72-hr algal EC(50) = 0.1 mg/l?

    a. Classify based on the fish LC(50) data.

    b. Classify based on the algal EC(50) data.

    c. Classify based on the mathematically determined average of the three EC/LC(50) data points.

    d. Classify based on a calculated ATE.

20. Which of the following represents the concentration to which nearly all workers can be exposed to in the workplace for and 8 hour day and 40 hour week without adverse effects?

    a. Time-weighted average limit (TWA)

    b. Short-term exposure limit (STEL)

    c. Ceiling limit (C)

    d. Biological limit value (BLV)

21. A "sensitizer" notation with a occupational exposure limit indicates which of the following?

    a. The limit is set to protect against dermal sensitization.

    b. The chemical can cause dermal and/or respiratory sensitization.

    c. The limit is set to protect against respiratory sensitization.

    d. Sensitization will not occur at levels below the limit.

22. Which of the following types of local exhaust ventilation is best for laboratory scale quantities of materials or substances that are acutely toxic by inhalation?

    a. Biological Safety Cabinet

    b. Laminar Flow Clean Bench

    c. Laboratory Fume Hood

    d. Canopy hood

23. Which of the following statements regarding risk based labeling is true?

    a. The risk based label communicates the likelihood of injury.

    b. The risk based label puts hazards in perspective.

    c. The risk based label excludes hazards based on very low risk.

    d. Risk based labeling applies to both acute and chronic hazards.

24. European Union specific statements (EUH statements) are included under which of the following sections of the label?

    a. Supplemental information

    b. Hazard statements

    c. Precautionary statements

    d. Signal word

25. In general terms, what is a national chemical inventory?

    a. A list of chemicals that may be manufactured, imported, or otherwise be used in commerce.

    b. A list of chemicals that are available for purchase.

    c. A list of hazardous chemicals manufactured in a specific economy.

    d. A detailed list of chemicals known to exist.

Knowledge Test Practice Exam Answer Key

1. B
2. B
3. C
4. B
5. A
6. D
7. C
8. A
9. A
10. B
11. A
12. D
13. D
14. C
15. D
16. A
17. B
18. C
19. B
20. A
21. B
22. C
23. C
24. A
25. A

THE PRACTICAL SKILLS ASSESSMENT

This part consists of two sub-parts. It is open book in that the GHS Rev 5 will be provided electronically for you use.

In the first part you need to classify one substance and one mixture following the GHS. For the substance you will be provided a complete set of data for the substance to compare to all the GHS hazard classes and categories. For the mixture you will be provided all needed mixture test data, substance data for hazard endpoints where calculations are needed for classification along with the overall classification for each substance in the mixture and the proportion. In both cases, you will need to assign all applicable physical, health and environmental hazard classes and categories.

The following is an example of a substance data set for your practice:

Classify this Substance Following The GHS Rev 5. Write the classification clearly, both hazard class and category.

Example Substance	
Organic/Inorganic:	Organic
Form:	Solid
Color:	Purple
Odor:	None
Viscosity:	Not Applicable
Boiling Point:	Not Applicable
Freezing Point:	180 C
Decomposition temperature:	250 C
Density:	1.5
Vapor Pressure:	Not Applicable
Vapor Density:	Not Applicable
Evaporation Rate:	Not Applicable
pH:	Not Applicable
Water Solubility:	10 g/L @ 20 C
Solvent Solubility:	Soluble in acetone
Octanol/Water Partition coefficient (Log Kow):	0.7
Auto-ignition Temperature:	>300 C
Flash Point:	Not Applicable
UEL:	Not Applicable
LEL:	Not Applicable
Burning Rate:	1 mm/sec
Burning Time:	60 seconds
Corrosion Data:	<1.0 mm/year at 55 C (saturated aqueous solution)
Reactivity Data:	Reacts with oxidizers releasing heat.
Stability Data:	Stable under normal conditions of storage and use
Decomposition Products:	Oxides of carbon and sulfur

Possibility of Hazardous Reaction:	None known
Exposure Limits:	0.5 mg/m3 TWA
Biological Limit Value:	None Established
Toxicological Information	
Oral Rat LD50:	525 mg/kg
Dermal Rabbit LD50:	>5000 mg/kg
Inhalation Rat LC50/4 hr:	>10 mg/L as dust no serious toxicity at highest dose tested
Skin Corrosion/Irritation:	In a 4 hour exposure in rabbits Mean value for erythema/eschar (from gradings at 24, 48 and 72 hours) : Rabbit 1 = 3.6, Rabbit 2 = 3.1, Rabbit 3 = 3.2 Mean value for oedema (from gradings at 24, 48 and 72 hours) : Rabbit 1 = 2.1, Rabbit 2 = 1.2, Rabbit 3 = 2.1
Eye Corrosion/Irritation:	3/3 rabbits mean scores: corneal opacity 0.5-0.9, iritis 0.5-0.9, conjunctival redness 2.0, conjunctival oedema 2.5, reversed in 14 days
Respiratory Sensitization:	No evidence of respiratory sensitization based on human experience
Skin Sensitization:	Positive guinea pig maximization test (60% responding at 0.5% intradermal dose)
Germ Cell Mutagenicity:	Negative AMES, Negative in-vivo mouse specific locus, Negative in-vitro mammalian chromosome aberration test
Carcinogenicity:	Negative in 2 year rat oral assay
Reproductive/Developmental Toxicity:	No adverse effects in studies with rats and rabbits
STOT Single Exposure:	No data available
STOT Repeat Exposure:	No adverse effects in 90 day rat oral study to a dose of 150 mg/kg/day
Ecological Toxicity Data	
Acute	
LC50 fish 96 hr:	125 mg/L
EC50 crustacea 48 hr:	280 mg/L
ErC50 algae 72 hr:	90 mg/L
Chronic	
Fish:	No data available
Crustacea:	No data available
Algae:	No data available
Degradability:	25% in 28 days OECD 302
BCF:	No data available

log Kow:	0.7

A: Acute Toxicity Oral Category 4; Skin Irritation Category 2; Eye Irritation Category 2A; Skin Sensitization Category 1A; Aquatic Toxicity Acute Category 3; Aquatic Toxicity Chronic 3

The following is an example of a mixture classification for your practice:

Classify the mixture below based on the data provided and/or classification given following the GHS mixture rules. Assume that the substance meets the classification criteria only for classifications given.

Example Mixture

95% Substance A / 5% Substance B

GHS Classification

Substance A

Acute Oral Toxicity Category 3 LD50 oral rat 250 mg/kg, LD50 dermal rabbit >5000 mg/kg

Eye Irritant Category 2A

Acute Aquatic Toxicity Category 2

Chronic Aquatic Toxicity Category 2

Substance B

Acute Dermal Toxicity Category 2 LD50 oral rat >5000 mg/kg, LD50 dermal rabbit 400 mg/kg

Skin Sensitizer Category 1B

Acute Aquatic Toxicity Category 1, M=1

A: Acute Toxicity Oral Category 3 (Calculated ATE = 263 mg/kg); Eye Irritation Category 2A; Skin Sensitization Category 1B; Aquatic Toxicity Acute Category 2; Aquatic Toxicity Chronic Category 2

In the second part you will author an actual SDS using a template for a chemical whose classification has been provided along with a complete data set. The template is a multiple choice format – you will mark the correct responses on the answer sheet from the choices presented in each section. You will not actually "write" the document manually. The data set will be very similar to the substance set above but in this case, the complete classification will have been provided. This SDS proficiency is based solely on the purple book (GHS) rev 5 for SDS format and content. The guidance in the GHS should be used to determine what information is placed where on the SDS. The correct answers in most sections will be based on consistency with the classification and labeling determined following the GHS. The best answers for Sections 5 and 6 are based on the NA Emergency Response Guidebook, which will be provided. We recognize that companies have internal policies governing certain standard information that is provided on the SDS that may not be hazard driven. For this proficiency, you will be graded on creating a SDS that is consistent with the hazard classification and the data provided.

In preparing Section 2 of the SDS template you will include ALL applicable pictograms, hazard and precautionary phrases without regard to precedence guidance.

Many sections are completed by selecting the BEST answer from the choices offered. In some cases you will be asked to indicate what type of information should be included for the field. There may be more than one correct answer.

Body of Knowledge

SDS and Label Authoring Registry

AIHA®
Protecting Worker Health

About AIHA®

Founded in 1939, the American Industrial Hygiene Association® (AIHA®) is one of the largest international associations serving the needs of industrial/occupational hygiene professionals practicing in industry, government, labor, academic institutions, and independent organizations.

For more information, visit www.AIHA.org

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Background

AIHA® and its selected members worked collaboratively to develop the technical framework, known as the Body of Knowledge (BoK), that outlines the knowledge and skills a competent person should possess and be able to demonstrate when authoring safety data sheets (SDS) and labels. In September 2015, a panel of subject matter experts was appointed to revise the SDS & Label Authoring BoK and develop a subsequent Job/Task Analysis (JTA) survey to collect input, perspective, and feedback from relevant stakeholders to identify the essential knowledge and skills required for competent SDS and label authoring. The subject matter expert project team included a subset of SDS and label authoring Registrants.

In December 2015, the JTA survey was made available to AIHA® SDS and Label Authoring Registrants. The survey results were used to finalize the content for the SDS and Label Authoring BoK.

The BoK document was approved by the subject matter expert project team June 2016.

SDS & Label Authoring

Occupational Definition

This document provides an organized summary of the collective knowledge and skills necessary for competent SDS and label authoring. This Body of Knowledge (BoK) will be used by AIHA to establish a framework to assist the prospective registrant in preparing for the exam. Prior to sitting for the SDS and Label Authoring Registry's Competency Assessment, the applicant should ensure that they are proficient in these knowledge areas.

This BoK is not intended to define or stipulate employer hiring criteria. It is the employer's responsibility to ensure that each employee understands his or her specific job and has met the minimum criteria established by relevant regulations, standards, and the specific industry, facility, or project.

Skills

Performance-based training incorporates performance tasks (performance assessments) that build on content knowledge. These demonstrations of knowledge and skills document competence.

Knowledge Test

The knowledge test consists of 75 multiple choice questions that evaluate your knowledge in areas in which a SDS and label authoring specialist should be proficient. These questions involve basic concepts in toxicology, ecotoxicology, industrial hygiene, chemistry, and emergency response for chemicals. You will be expected to perform mathematical calculations and conversions related to hazard classification and SDS. A formula sheet will be provided. It will contain all the formulas that you will need and all the Globally Harmonized System of Classification and Labeling of Chemicals international standard (GHS) classification tables or decision logic charts needed for substance and mixture classification questions. This BoK provides a blueprint of the type of questions you can expect in each knowledge area.

Knowledge Areas

Table 1 describes the knowledge and skills that constitute competent SDS and label authoring.

1.0 Math and Science (19%)

1.A. General mathematics & computation

1.A.1. Calculate composition percentages

1.A.2. Calculate percentages of pure substances in mixtures of mixtures

1.A.3. Convert and calculate ppm, ppb, and ppt into weight/volume percent

1.A.4. Convert ppm to mg/L, mg/mL, and g/L; and vice versa for liquids and solids

1.A.5. Convert ppm to mg/L or mg/m3 and vice versa for gases, vapors, dust and mists

1.A.6. Understand the relationship between density and specific gravity

1.A.7. Convert temperature in Celsius to Fahrenheit and vice versa

1.A.8. Understand standard unit/metric system

1.B. General Chemistry

1.B.1. Understand the differences between atoms elements and compounds

1.B.2. Demonstrate an understanding of the major types of chemical identifiers and their use (ex: CAS numbers, UN Numbers, EINECS, etc.)

1.B.3. Demonstrate an understanding of the main types of compounds (organic, inorganic, monomers, polymers, surfactants, solvents, acid, bases)

1.B.4. Identify key characteristics of the main types of organic compounds (Alkanes, Alkenes, Alkynes, Aromatic Hydrocarbons, Alcohols, Amines, Acids, Amides, Esters, Ethers, Halogens, Nitros, Aldehydes, Ketones, Isocyanates, Peroxides)

1.B.5. Understand the main chemical and physical properties included on a SDS under the GHS

1.B.6. Demonstrate an understanding of the various types of solubility (highly soluble, soluble, slightly soluble, nonsoluble)

1.B.7. Understand what pH is and how it is calculated

1.B.8. Understand and identify reaction products

1.B.9. Understand the differences between stability and reactivity

1.B.10. Differentiate between the three physical forms (gas, liquid, solid) and understand the hazard potentials for each

1.B.11. Understand the route of exposure potential for the different physical forms

1.B.12. Understand the meaning of physical property with regard to the hazard of the property

1.B.13. Understand the meaning of physical properties and their test methods to determine the end point (e.g. vapor pressure, boiling point, flash point)

1.B.14. Understand the behaviors of mixtures vs substances

1.B.15. Understand how temperature and pressure impact other hazards outside the scope of the specifically defined hazard classes

2.0 Hazard Communication (20%)

2.A. GHS Concepts

2.A.1. Understand the scope of the GHS

2.A.2. Understand the structure of the purple book

2.A.3. Demonstrate an understanding of the scope, application and limitations of the GHS

2.A.4. Apply knowledge of GHS concepts including the building block approach and application

2.A.5. Understand GHS definitions like hazard class, hazard category, weight of evidence, etc.

2.A.6. Demonstrate an understanding of which elements of the GHS are applicable to the different sectors (transport, workplace, consumer products)

2.A.7. Apply knowledge of GHS Classification Principles for substances and mixtures

2.A.8. Demonstrate an understanding of using cut-off values

2.A.9. Understand labeling concepts

2.A.10. Demonstrate an understanding of the general guidelines for SDS reader comprehension

2.A.11. Demonstrate an understanding of the relationship between each section and piece of data on the SDS document so that consistency can be achieved throughout the document

2.A.12. Identify data sources on the SDS (mixture testing versus component data)

2.A.13. Understand the term article

2.A.14. Demonstrate an understanding of the building block approach

2.A.15. Understand and identify the harmonized GHS label elements

2.B. SDS Content & Label

2.B.1. Demonstrate an understanding of identifying chemicals (IUPAC, common names, CAS, EC)

2.B.2. Understand the concepts found on a safety data sheet and the audience(s) for each section

- **2.B.2.a** Identification (Product Name/Manufacturer Information including Emergency Contact Information/Recommended Use/Restricted Use)
- **2.B.2.a** Hazard Identification
- **2.B.2.b** Composition
- **2.B.2.c** First-aid measures
- **2.B.2.d** Fire-fighting measures
- **2.B.2.e** Accidental release measures
- **2.B.2.f** Handling and storage
- **2.B.2.g** Exposure Controls and Personal Protective Equipment
- **2.B.2.h** Physical and chemical properties
- **2.B.2.i** Stability and reactivity
- **2.B.2.j** Toxicological information
- **2.B.2.k** Ecological information
- **2.B.2.l** Disposal considerations
- **2.B.2.m** Transport information
- **2.B.2.n** Regulatory Information
- **2.B.2.o** GHS labeling requirements
- **2.B.2.p** NFPA or HMIS ratings (Alternative labeling systems)
- **2.B.2.q** Other information

2.B.3. Know the process in which an SDS is developed (Order of section development)

2.B.4. Know how to review an SDS for internal consistency

2.B.5. Understand the sections, required format, and the content of a GHS Safety data sheet

2.B.6. Demonstrate knowledge for the selection of label elements (pictogram(s), signal word, hazard statement(s) and precautionary statement(s) based on a GHS Classification

2.B.7. Know the elements of a GHS compliant label

2.B.8. Understand how a GHS label is developed using the tables in Annex 3 of the GHS

2.B.9. Know the order of precedence for the label elements in the GHS

3.0 Physical Hazards (9%)

3.1. Apply knowledge of the 17 physical hazard classes and when to use them

3.2. Understand the use of ISO 10156:2010 in calculating the flammability of gas mixtures under GHS

3.3. Understand how the hazard classes under the GHS physical hazards section relate to and can be used to determine the transportation information - hazard class, packing group, etc. (**Note: Formal training on transportation regulations is required before an SDS author can apply this to section 14 of an SDS.)

3.4. Familiarize yourself with the test methods used to determine physical hazards and how to interpret test data for the various classes

3.5. Demonstrate an understanding of Hazards Not Otherwise Classified (HNOC) and where they are implemented

3.6. Demonstrate an understanding of combustible dust

4.0 Health Hazards (21%)

4.A. General Concepts

4.A.1. Understand data conversion (1 hour to 4 hour for inhalation toxicity data, ppm to mg/L for vapor toxicity)

4.A.2. Distinguish between the different forms of matter (gas, vapor, mist, dust)

4.A.3. Understand the relevant ingredients concept for untested mixture classification in the hazard classes that use additivity (Acute Toxicity, Skin Corrosion/Irritation, Serious Eye Damage/Eye Irritation, Target Organ Toxicity – Single Exposure Category 3, Aspiration Hazard, and Hazardous to the Aquatic Environment)

4.A.4. Convert range data or acute toxicity category to a point estimate for mixture calculations

4.A.5. Understand how to properly handle ingredients with unknown acute toxicity

4.A.6. Apply knowledge of the 10 health hazard classifications and when to use them for substances

4.A.7. Understand the GHS tiered approach to classifying mixtures (e.g. tested mixtures, bridging principles, untested mixture calculations)

4.A.8. Demonstrate an understanding of HNOCs and where they are implemented

4.B. General Toxicology Concepts

4.B.1. Understand the term toxicology

4.B.2. Understand how chemicals move into and out of the body: absorption, distribution, metabolism and excretion

4.B.3. Understand dose-response relationship

4.B.4. Understand the threshold response concepts (NOEL, NOAEL, LOAEL)

4.B.5. Understand the adverse health effect concept

4.B.6. Distinguish between immediate (acute) vs. Delayed (chronic) effects

4.B.7. Distinguish between Local vs. Systemic effects

4.B.8. Distinguish between Reversible vs. Irreversible effects

4.B.9. Understand toxicity tests

4.B.10. Understand preferred species for acute toxicity tests

4.B.11. Understand when Additivity is used and when it is not (skin corrosion/irritation, serious eye damage/eye irritation)

4.B.12. Understand weight of evidence

4.C. General Biology

4.C.1. Demonstrate an understanding of the structure and function of target organs (e.g. respiratory system, kidney, liver, nervous system)

5.0 Environmental Hazards (8%)

5.A General Ecotoxicology Concepts

5.A.1. Understand the toxicity endpoints: LD50, LC50, EC50, NOEC

5.A.2. Understand and identify the different methods and durations for acute aquatic toxicity testing and the organisms used

5.A.3. Understand and identify the different methods of classification for chronic aquatic toxicity testing and the organisms used

5.A.4. Demonstrate an understanding of persistence testing (i.e., biodegradation, hydrolysis, photolysis)

5.A.5. Demonstrate an understanding of bioconcentration and bioaccumulation (logKow/Pow)

5.A.6. Demonstrate an understanding of degradation

5.A.7. Understand the concept of M factor

5.A.8. Understand how to apply the criteria for Ozone Depleting Potential under the GHS

5.A.9. Apply criteria for classifying substances for acute and chronic aquatic toxicity potential including the concept of different trophic levels (fish, aquatic inverts, aquatic plants)

5.A.10. Understand the GHS tiered approach to classifying mixtures (e.g. tested mixtures, bridging principles, untested mixture calculations) (i.e. Summation and Additivity)

5.A.11. Understand how to properly handle ingredients with unknown hazards to the aquatic environment

6.0 Industrial Hygiene & Safety (12%)

6.1. Determine which exposure limit to include in the SDS based on the exposure limits given

6.2. Understand the types of threshold limit values (i.e., TWA, STEL, Ceiling Limit, IFV, Excursions, BEI, Respirable Fibers, Dust Limits – total, inhalable, thoracic fraction and respirable)

6.3. Understand significant routes of exposure for various physical states

6.4. Understand the applicability of engineering controls (i.e., ventilation)

6.5. Demonstrate an understanding of the PPE recommendations related to hazards, quantity, and conditions of use

6.6. Understand and apply appropriate first-aid measures based on classification

6.7. Demonstrate an understanding of special treatments for exposure

6.8. Consider special needs that a physician should be made aware of when completing the first-aid section (section 4) of the SDS

6.9. Differentiate between suitable/unsuitable controls for fire types

6.10. Understand and identify the specific hazards arising from burning chemical fires

6.11. Demonstrate an understanding of compatible and incompatible chemical placement

6.12. Select precautionary statements for safe handling based on classification and physical properties

6.13. Recommend personal precautions, protective equipment and protective measures for spilled product(s)

6.14. Understand how stability and reactivity relate to an SDS

6.15. Identify the drivers behind chemical incompatibility

6.16. Apply knowledge of chemical incompatibility

7.0 Risk Analysis (2%)

7.1. Understand the relationship between risk, hazard, and exposure

7.2. Understand how consumer product labeling can be based on the likelihood of injury (see GHS Annex 5)

7.3. Understand how the term "biologically available" can be considered when performing hazard classification

8.0 International GHS Implementation, Associated Regulations & Consensus Standards (8%)

8.1. Understand the US OSHA specific hazard classes

8.2. Demonstrate an understanding of environmental regulations that would impact Section 15 of the SDS sheet (i.e., CERCLA, SARA, TSCA, etc.)

8.3. Understand SDS content required by EPCRA (SARA 313)

8.4. Demonstrate an understanding of dangerous goods transportation

8.5. Identify and list OEL/BEI for different areas/countries (i.e. PEL, TLV, MAK, REL)

8.6. Demonstrate understanding of Right to Know Laws

8.7. Apply general understanding of disposal regulations

8.8. Demonstrate an understanding of Inventory and chemical control laws (US TSCA, Canadian DSL, NDSL, etc.)

8.9. Demonstrate basic knowledge of EU CLP Annex VI

8.10. Understand the characteristics of a study that adds to its weight of evidence for classification (e.g., Good Laboratory Practice (GLP), statistical significance, etc.)

8.11. Know requirements for OSHA's Hazard Communication Standard 2012

8.12. Understand which ingredients or impurities must be disclosed in an OSHA HCS 2012 SDS

8.13. Understand what information may be claimed as trade secret under OSHA HCS 2012

8.14. Be familiar with the comprehensibility concepts for SDSs and labels (e.g., ANSI Z1291/Z4001)

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MONTH DAY

In Person: check the Registry website
OR
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Step 6: Sit for Exam

- Two 2-hour parts taken online
- Laptop required
- e-copy of GHS provided

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B: Classify Mixture
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Attachment E

Who We Are

The Center for Safety and Health Sustainability, established in 2010, is a 501(c)3 nonprofit corporation committed to advancing the safety, health and sustainability of the global workplace.

Representing over 100,000 occupational safety and health professionals in over 70 countries, the Center's board and advisory council represent a global collaborative effort of the following organizations:

American Industrial Hygiene Association (AIHA)

American Society of Safety Engineers (ASSE)

Canadian Society of Safety Engineering (CSSE)

Institution of Occupational Safety and Health (IOSH) (United Kingdom)

BrownFlynn

European Bank for Reconstruction and Development

National Institute for Occupational Safety and Health (NIOSH) (United States)

ORCSHE Strategies, LLC

Sustainability Accounting Standards Board (SASB)

WSH Institute (Singapore)

Support us in our efforts to help create safer and healthier workplaces around the world by making a donation at www.centershs.org/donate.

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cshs

Center for **Safety & Health Sustainability**

For all organizations to consider the safety, health and well-being of workers, customers and the community as part of their sustainable business practice.

AIHA *Protecting Worker Health* · iosh

OSH in Sustainability

A sustainable organization is a safe organization.

Organizations are increasingly adopting the "triple bottom line" – or social, economic, and environmental – approach to taking responsibility for sustainability. Unfortunately, when an organization considers the "social" aspect of sustainability, occupational safety and health (OSH) receives very little attention, if any at all.

Yet every year more than 2 million people die from occupational accidents or work-related diseases and there are millions more cases of non-fatal occupational accidents and diseases.

The Center for Safety and Health Sustainability was established to create awareness of the fact that a sustainable organization cannot be one that does not ensure safe and health working conditions for its employees and contractors. It also provides occupational safety and health professionals with a stronger voice in shaping sustainability policies—both in business and in public policy.

Reporting

Organizations tell the rest of the world about their sustainable business practices through sustainability reporting through various sustainability frameworks.

The Center has identified three major weaknesses with regard to reporting on safety and health sustainability performance metrics:

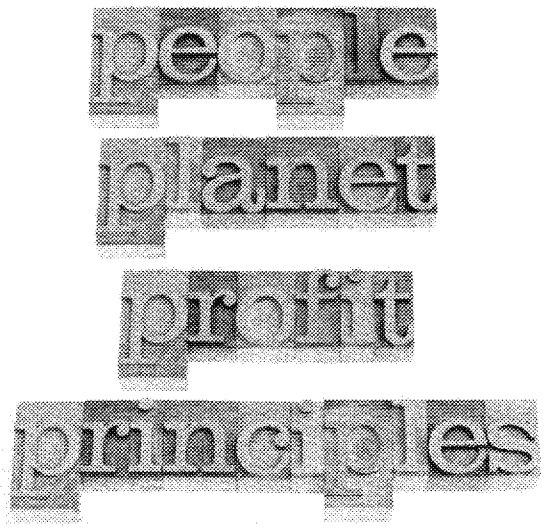
1. No agreement exists on the key performance indicators to measure OSH performance.
2. Current OSH reporting practices lack uniformity, making it difficult to compare performance across organizations.
3. The metrics currently reported on are too limited in scope and focus predominantly on results.

Goals

- To provide a strong voice and comprehensive leadership for worker safety and health in shaping sustainability policies.
- To educate the business community on the importance of worker safety as part of good corporate governance and corporate social responsibility/ sustainability.
- To provide new insights into the measurement, management, and impact of worker safety and health sustainability.
- To be a recognized thought leader for sustainability and corporate social responsibility.

Major Center Activities

- Conducting research on current trends in OSH sustainability reporting.
- Providing insight and leadership in occupational safety and health (OSH) measurement within sustainability reporting structures.
- Increasing the visibility of supply-chain worker safety and health concerns via traditional and social media.
- Attending, presenting, and maintaining high visibility for OSH at major international sustainability conferences.
- Providing education and guidance to a wide variety of organizations, including Global 500 corporations.
- Promoting sustainability visibility within the OSH community.
- Developing an OSH Sustainability benchmarking database.



The Need for Standardized Sustainability Reporting Practices:

Issues Relating to Corporate Disclosure of Information on Occupational Health & Safety Performance

A report from the Center for
Safety & Health Sustainability

June 2017

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The Center for Safety & Health Sustainability (CSHS), established in 2010, is a 501(c)(3) nonprofit organization committed to advancing the safety and health sustainability of the global workplace. CSHS engages safety and health partners around the world to work toward establishing minimum standards that help reduce workplace injuries and ill health. A collaborative effort founded by American Society of Safety Engineers, American Industrial Hygiene Association and Institution of Occupational Safety and Health, CSHS represents more than 100,000 workplace safety and health professionals in over 120 countries.